COLORADO
Prescription Drug Affordability Board
Division of Insurance

Affordability Review Summary Report: Cosentyx

June 14, 2024

Draft Submitted to: the Colorado Prescription Drug Affordability Board

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Executive Summary

Affordability Review Summary Report Findings

Cosentyx (secukinumab), first approved by the United States Food and Drug Administration (FDA) in 2015, is an interleukin inhibitor and is used to treat ankylosing spondylitis, non-radiographic axial spondyloarthritis, hidradenitis suppurativa, plaque psoriasis in patients 6 years or older, psoriatic arthritis in patients 2 years of age and older, and enthesitis-related arthritis. At the time of this publication, Cosentyx does not have any FDA-approved indications for rare diseases or active orphan drug designations.

Therapeutic alternatives for Cosentyx, as identified through professional medical guidelines, with utilization reported in the Colorado All Payer Claims Database (APCD) in 2022 are: Bimzelx, Ilumya, Siliq, Skyrizi, Stelara, Taltz, and Tremfya. Patients and caregivers, as well as individuals with scientific and medical training, provided input that patients prefer many treatment options to identify the medications that work for them. When compared to a placebo, Cosentyx has shown improvements in symptoms for each of its six indications. For some indications, there is evidence that Cosentyx and its in-class therapeutic alternatives are associated with beneficial treatment effects when compared to other prescription drug treatments not in class.

In passing Senate Bill 21-175, the legislature recognized the importance of evaluating both the effectiveness of a drug, as well as its cost to consumers and the health care system. Cosentyx's wholesale acquisition cost has increased 116.64%, from [redacted] per unit at its launch in January 2015 to [redacted] per unit in January 2024, which is greater than the increase in inflation for the same time period. 26% of insurance carriers who submitted information to the Colorado All Payer Claims Database (APCD) reported that Cosentyx was one of the top 15 prescription drugs that raised premiums for all covered lives. Cosentyx has also appeared in other states' assessments of the costliest drugs for that state, including being among the costliest drugs

In Colorado in 2022, Cosentyx was used by 1,128 patients compared to its in-class therapeutic alternatives, Ilumya (31), Skyrizi (1,028), Stelara (1,700), Taltz (1,140), and Tremfya (445) and it saw a large increase in utilization from 2018 to 2022 (over 140%). According to 2022 APCD data, Cosentyx cost $46,948 per patient and over $52,957,875 in total. In that year, the average annual out-of-pocket cost for patients with commercial insurance was $2,801. In 2023, Novartis, the manufacturer of Cosentyx, reported total sales of Cosentyx were $4.980 billion, a 4% increase from $4.788 billion in 2022, including $2.636 billion in US sales and $2.344 billion internationally.

The following report and its appendices provide detailed evidence necessary for the Board's consideration of whether Cosentyx is unaffordable to Coloradans.

Board Deliberation and Vote Summary

After receiving and reviewing evidence in support of the affordability review components set forth in statute and rule, on June 14, 2024, the Colorado Prescription Drug Affordability Board (the Board) acknowledged there was sufficient evidence to proceed with deliberations for the Cosentyx affordability review. The Board then deliberated whether the use of Cosentyx was unaffordable for Colorado consumers.

During deliberations, Board members noted that the high out-of-pocket cost for Cosentyx, the rapid increase in WAC, and the unreliability of patient assistance programs provided evidence that the drug is unaffordable to Colorado consumers. Deliberation also included discussion of:

- Cosentyx is a highly useful and effective medication for all approved indications.
- Cosentyx is among the costliest drugs in Colorado and is used broadly across the state.
- Carriers reported Cosentyx as one of the top 15 drugs to cause an increase in premiums.
- Cosentyx's copayment is the highest among its therapeutic alternatives.

- There is significant out-of-pocket cost to Coloradans.
- Cosentyx's wholesale acquisition cost (WAC) is increasing faster than therapeutic alternatives, and is significantly outpacing inflation.
- Cosentyx's manufacturer offers patient assistance programs that patients rely on, but these may not be sustainable and reliable on a long-term basis.

After deliberation and hearing public comment from five individuals, the Board voted 4-0 that the use of Cosentyx consistent with the labeling approved by the FDA or with standard medical practice is unaffordable for Colorado consumers. Dr. Sami Diab recused himself from the deliberation and vote due to a conflict of interest.

To view the meeting recording in full, see:

https://us06web.zoom.us/rec/share/lHfsYBzjDwmiO6gShjlXtRlzZRZ-RwvolWkwVyrU_j1HRo_FtvLAF8ULwlYwfgrv.v5K6QjjD5f4iP7vQ

Introduction

The Colorado Prescription Drug Affordability Board (the Board) was established in 2021 through the passage of Senate Bill 21-175. Governor Polis appointed five members to the Board in September 2021. Since then, the Board has appointed members to the 15-person Prescription Drug Affordability Advisory Council (the Advisory Council) and hosted a five-part learning series in spring 2022 to provide Board members, Advisory Council members, and interested stakeholders foundational knowledge necessary to implement a successful new prescription drug affordability program. The Board has also promulgated five rules to implement statutory requirements, and developed five policies to guide the program.

One of the Board's duties is to perform affordability reviews of prescription drugs as described in section 10-16-1406, C.R.S. This section outlines the Board's four steps in conducting affordability reviews:(1) identification of eligible drugs, (2) selection of drugs for affordability reviews, (3) conducting affordability reviews on selected drugs, and (4) determining if use of the selected drugs are unaffordable for Colorado consumers.

The first step - identification of prescription drugs eligible for affordability reviews - was completed when the Board approved the final list of prescription drugs eligible for affordability reviews on June 9, 2023. The second step - selection of prescription drugs for affordability reviews - was completed when the Board selected five drugs for affordability reviews on August 4, 2023. This report has been prepared by Board staff to assist the Board in completing the third and fourth steps of the affordability review process for the prescription drug, Cosentyx.

This report of the affordability review for Cosentyx was conducted in accordance with 3 CCR 702-9, Part 3.1.E.6. Additionally, this report contains appendices with detailed information for each of the fifteen criteria the Board shall and may consider as a part of its affordability review, to the extent practicable.

Report Structure

About This Report

The main body of the Affordability Review Summary Report is divided into three profiles: a therapeutic and utilization profile; a cost and price profile; and an access to care profile. The profiles contain information from the fifteen statutory and regulatory components the Board considers as a part of an affordability review. The profiles were identified by Board members and Board staff as a way to present affordability

review evidence in a commonsense manner. While these profiles incorporate all fifteen components the Board considers during affordability reviews, additional information is provided for each of the fifteen components in the appendices, with each component having an individual appendix. More information on the structure of each profile and the appendices is provided in the sections below.

While several components lend themselves to inclusion in only one profile, three components inform all profiles contained in the Summary Report. Those components, and information regarding the type and volume of feedback Board staff received, are summarized below:

- Input from patients and caregivers - Board staff gathered input from two patients and caregivers at one public meeting on September 21, 2023. Additionally, 15 patients and caregivers completed surveys regarding the health and financial effects of Cosentyx, and many of these patients and caregivers also attended the public meetings.
- Input from individuals with scientific and medical training - Board staff gathered input from one individual with scientific or medical training at one public meeting on September 21. Additionally, three individuals with scientific & medical training completed surveys regarding the health and financial effects of Cosentyx.
- Voluntarily submitted information - three patients, caregivers, and other entities submitted voluntary information. Novartis AG, the manufacturer of Cosentyx, also voluntarily submitted information. For readability the manufacturer is referred to as Novartis throughout the summary report and appendices. Note: no assessment was conducted of accuracy of voluntarily submitted information or the extent to which the information applies to Coloradans.

The Summary Report and Appendices may contain proprietary, confidential, and trade-secret information. Such information is redacted in public reports.

Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Cosentyx's clinical efficacy and the people who use it. This section provides information regarding Cosentyx's indication, utilizer profile, health equity impact, and therapeutic alternatives. Affordability review components present in this profile include information from Appendices B, G, H, I, J, and L.

Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Cosentyx, as well as what different entities pay for Cosentyx. This profile also contains information on Cosentyx's financial effects on health, medical, and social service costs. Affordability review components present in this profile include information from Appendices A, B, D, E, H, I, J, K, and O.

Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Cosentyx and whether there is evidence that the causes of access to care concerns may be related to Cosentyx's price or cost. This profile includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design. Affordability review components present in this profile include information from Appendices A, B, C, E, F, H, I, J, K, M, and N.

Appendices

This report contains an appendix for each of the fifteen components the Board is to consider as a part of affordability reviews, as well as a last appendix, Appendix P - Data Sources and Limitations. Descriptions of the appendices related to the fifteen affordability review components are outlined below.

Table 1

Appendices and Relevant Statutory, Rule, and Policy Guidance for Affordability Review Components

Component Name	Component Details
Appendix A: Current WAC & Change in WAC	The Board shall consider the wholesale acquisition cost of the drug. C.R.S. § 10-16-1406(4)(a).
Appendix B: Therapeutic Alternatives	The Board shall consider the cost and availability of therapeutic alternatives to the prescription drug in the state. C.R.S. § 10-16-1406(4)(b).
Appendix C: Price Effect on Access	The Board shall consider the effect of the price on Colorado consumers' access to the prescription drug. C.R.S. § 10-16-1406(4)(c).
Appendix D: Relative Financial Effects	The Board shall consider the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. C.R.S. § 10-16-1406(4)(d).
Appendix E: Patient Copayment & Other Cost Sharing	The Board shall consider the patient copayment or other cost sharing of the drug. C.R.S. § 10-16-1406(4)(e).
Appendix F: Safety Net Providers	The Board shall consider the impact on safety net providers if the prescription drug is available through section 340B of the federal "Public Health Service Act", Pub.L. 78-410. C.R.S. § 10-16-1406(4)(f).
Appendix G: Orphan Drug Status	The Board shall consider orphan drug status. C.R.S. § 10-16-1406(4)(g).
Appendix H: Patients & Caregivers	The Board shall consider input from patients and caregivers affected by the condition or disease that is treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(I).
Appendix I: Individuals with Scientific & Medical Training	The Board shall consider input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board. C.R.S. § 10-16-1406(4)(h)(II).
Appendix J: Voluntarily Submitted Information	The Board shall consider any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide. C.R.S. § 10-16-1406(4)(i).
Appendix K: Rebates, Discounts, and Price Concessions	The Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.i.
Appendix L: Health Equity	The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.ii.

Component Name	Component Details
Appendix M: Information from HCPF	The Board shall consider information from the Department of Health Care Policy and Financing, including additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub. L. 78-410. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, Part 3.1.E.2.j.iii.
Appendix N: Non-Adherence & Utilization Management	The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. C.R.S. § 10-16-1406(4)(j); 3 CCR 702-9, 3.1.E.2.j.iv.
Appendix O: Pricing Information	The Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug. C.R.S. § 10-16-1406(6). The Board may access pricing information for prescription drugs by: (I) accessing publicly available pricing information from a state to which manufacturers report pricing information; (II) accessing available pricing information from the all-payer health claims database and from state entities; and (III) accessing information that is available from other countries. C.R.S. § 10-16-1406(7)(a).

Cosentyx Therapeutic and Utilization Profile

The Therapeutic and Utilization Profile includes information about Cosentyx's clinical efficacy and the people who use it. This section provides information regarding Cosentyx's indication, utilizer profile, health equity impact, and therapeutic alternatives.

Indications

Cosentyx has six FDA-approved indications:[1]

- **Plaque psoriasis (PsO)** - moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy (FDA approval for adults in 2015, FDA approval for children in 2021).
- **Psoriatic arthritis (PsA)** - active psoriatic arthritis in patients 2 years of age and older (FDA approval in 2021). In children and teenagers, this indication is often referred to as juvenile psoriatic arthritis (JPsA).
- **Enthesitis-Related Arthritis (ERA)** - active enthesitis-related arthritis in pediatric patients 4 years of age and older (FDA approval in 2021).
- **Ankylosing spondylitis (AS)** - adults with active ankylosing spondylitis (FDA approval in 2016)
- **Non-Radiographic Axial Spondyloarthritis (nr-axSpA)** - adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation (FDA approval in 2020).
- **Hidradenitis Suppurativa (HS)[2]** - adults with moderate to severe hidradenitis suppurativa (FDA approval in 2023).

For context, all of the above indications are autoimmune inflammatory diseases. Additionally, there is some overlap among these indications. Plaque psoriasis is the most common form of the chronic skin condition, psoriasis.[3] Psoriasis is also associated with PsA; the majority of patients who develop PsA already have some form of psoriasis (PsO or another psoriasis).[4] JPsA and ERA are two different types of juvenile idiopathic arthritis (JIA)[5], an umbrella term for chronic arthritis in children.[6] AS and nr-axSpA are both types of axial spondyloarthritis.

Cosentyx is an IL-17A inhibitor and is classified by the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system as interleukin inhibitors[7]. Additional information is provided below for each FDA-approved indication.

Plaque Psoriasis

Plaque psoriasis (PsO) is the most common type of psoriasis, accounting for more than 80% of cases. Psoriasis affects both men and women, with earlier onset in women and those with a family history. An estimated 60 million people have psoriasis worldwide, and the condition is more common in high income areas and areas with older populations.[8]

The National Psoriasis Foundation describes the appearance of psoriasis plaques as raised, inflamed, and scaly patches of skin that may also be itchy and painful.[9] On white skin, plaques typically appear as raised,

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[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

[2] Due to the relatively sparse research and very recent FDA approval of Cosentyx for treatment of HS, some sections of this summary report and the appendices may have less information for this indication.

[3] https://www.niams.nih.gov/health-topics/psoriasis

[4] https://www.niams.nih.gov/health-topics/psoriatic-arthritis

[5] https://www.niams.nih.gov/health-topics/juvenile-arthritis

[6] https://pubmed.ncbi.nlm.nih.gov/31779842/

[7] https://www.whocc.no/atc_ddd_index/?code=L04AC&showdescription=no

[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140694/

[9] https://www.psoriasis.org/plaque/

red patches covered with a silvery white buildup of dead skin cells or scale, and on skin of color, the plaques may appear darker and thicker and more of a purple or grayish color or darker brown. Plaques can appear anywhere on the body, although they most often appear on the scalp, knees, elbows, and torso. Plaques generally appear symmetrically on the body, affecting the same areas of the body on the right and left sides.[10] Patients with psoriasis may also present with other chronic conditions such as Crohn's disease, psoriatic arthritis, psychological disorders, and uveitis.[11]

Treatment options for plaque psoriasis include topicals, phototherapy, oral treatments, and biologics. Recognition and management of comorbidities (such as psoriatic arthritis, psychological, cardiovascular and hepatic diseases) is an essential part of holistic care for individuals with psoriasis.[12] Overall treatment goals include treating existing lesions to minimize pain and drainage, decreasing the frequency of recurrence, and preventing disease progression.[13]

Plaque psoriasis is also the most common clinical form of psoriasis in children.[14] One article reported that approximately 70% of children with psoriasis present with chronic plaque psoriasis.[15] Nearly 40% of adult patients with psoriasis have reported having the condition in childhood, with at least one-third of the patients showing symptoms of psoriasis before the age of 16 years.[16]

One study states that pediatric patients with psoriasis are also likely to have various comorbidities such as hyperlipidemia, hypertension, diabetes mellitus, rheumatoid arthritis, and Chrohn's disease. The long-term comorbidities associated with psoriasis can place a great burden on the physical and mental wellbeing of children with psoriasis beyond the symptoms of psoriasis itself, therefore it is encouraged to screen patients periodically and receive treatment not only for their skin lesions but also for comorbidities.[17]

Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, inflammatory disease of the joints and entheses, where tendons and ligaments connect to bone, and is linked with psoriasis.[18] PsA affects men and women almost equally with a peak age at onset of 40 and 50 years, though it may also affect children.[19] For many people, it starts about 10 years after psoriasis develops, but some develop PsA first or without ever developing or noticing psoriasis.[20]

PsA affects multiple organ systems including peripheral and axial joints, skin, and nails, and is associated with comorbidities such as osteoporosis, uveitis, subclinical bowel inflammation, and cardiovascular disease.[21] Joint pain, stiffness, and swelling are the main symptoms of PsA, and disease flares can alternate with periods of remission.[22] PsA is similar to rheumatoid arthritis (RA) in symptoms and inflammation but it tends to affect fewer joints than RA.[23]

Diagnosing psoriatic arthritis begins with a physical exam to look for swollen or painful joints, and nail and skin changes. X-rays or scans like ultrasound, MRI or CT can show joint damage. Blood tests may help rule

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[10] https://www.psoriasis.org/plaque/
[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4323693/
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140694/
[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8140694/
[14] https://www.uptodate.com/contents/psoriasis-in-children-epidemiology-clinical-manifestations-and-diagnosis?topicRef=112983&source=see_link
[15] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049
[16] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132900/
[17] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049
[18] https://www.psoriasis.org/about-psoriatic-arthritis/
[19] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6758836/
[20] https://www.psoriasis.org/about-psoriatic-arthritis/
[21] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6758836/
[22] https://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/symptoms-causes/syc-20354076
[23] https://www.hopkinsmedicine.org/health/conditions-and-diseases/arthritis/psoriatic-arthritis

out other diseases, and a skin biopsy can confirm psoriasis.[24] Though there is no cure, a growing range of treatments are available to help stop the disease progression, lessen pain, protect joints, and preserve range of motion. Early recognition, diagnosis, and treatment of PsA can prevent or limit the extensive joint damage that can occur in later stages of the disease.[25]

Juvenile Idiopathic Arthritis (JIA) Subsets

Juvenile idiopathic arthritis (JIA) is an umbrella-term describing a group of conditions characterized by chronic arthritis beginning before the age of 16 years, persisting for at least 6 weeks, and having no other identifiable cause.[26] Juvenile Psoriatic Arthritis (JPsA) and Enthesitis-Related Arthritis (ERA) are included among the seven JIA subtypes outlined by the International League of Associations for Rheumatology (ILAR) classification for JIA.[27]

Juvenile Psoriatic Arthritis

Juvenile psoriatic arthritis (JPsA) is a relatively rare condition in childhood as it represents approximately 5% of the entire JIA population.[28] JPsA most often appears between the ages of 11 and 12, and girls are more likely to develop it when they are younger and boys when they are older.[29]

Symptoms can vary considerably but may include stiffness, pain, and swelling in one or more joints, pitted nails, stiffness and limited range of motion, fatigue, swelling, redness and pain in the eyes, and a red itchy rash on the joints, scalp, face, and trunk.[30] Early diagnosis improves the chances of successful treatment and the prevention of joint damage and other complications. Treatment for JPsA aims to relieve pain, reduce swelling, and prevent further damage to the joints.[31]

The literature is inconsistent regarding JPsA, and there is debate among rheumatologists whether it is a distinct entity within JIA.[32] The few studies that have compared the clinical characteristics and genetic determinants of JPsA with those of the other JIA categories have obtained competing findings. The debate on the categorization of JPsA as a distinct entity within JIA classification is still ongoing and has prompted the revision of its current classification.[33] Due to the relatively sparse research and very recent FDA approval of Cosentyx for treatment of JPsA, some sections of this summary report and the appendices may have less information for this indication.

Enthesitis-Related Arthritis

Enthesitis-related arthritis (ERA) is a subtype of JIA that is characterized as the involvement of peripheral joints, entheses, and the axial skeleton, and is considered the counterpart of adult spondyloarthropathies.[34] ERA represents 5–30% of all cases of JIA and belongs to the spectrum of the disorders included in the group of juvenile spondyloarthritis.[35] ERA has a peak age of onset of 12 years, and boys are affected more often than girls, accounting for 60% of cases.[36]

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[24] https://rheumatology.org/patients/psoriatic-arthritis
[25] https://www.psoriasis.org/about-psoriatic-arthritis/
[26] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[27] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9199423/
[29] https://www.medicalnewstoday.com/articles/322612#causes-and-risk-factors
[30] https://www.medicalnewstoday.com/articles/322612#symptoms
[31] https://www.medicalnewstoday.com/articles/322612#treatment
[32] https://www.jrheum.org/content/94/11
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9821505/
[34] https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-022-06028-8
[35] https://www.mdpi.com/2227-9067/10/10/1647
[36] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3882059/

Diagnosis is established by the presence of enthesitis and arthritis, or by the presence of arthritis and at least two of the following: sacroiliac pain and/or spinal inflammation, acute anterior uveitis, presence of the HLA-B27 antigen, a family history of uveitis, and spondyloarthropathy, or sacroiliitis with inflammatory bowel disease in a first-degree relative.[37] Treatment regimens for ERA, many of them based on adults with rheumatoid arthritis and ankylosing spondylitis, include the use of nonsteroidal anti-inflammatory drugs, disease-modifying antirheumatic drugs, and biologic agents either individually or in combination.[38]

Axial Spondyloarthritis Subsets

Axial spondyloarthritis (axSpA), is an inflammatory disease that causes inflammation in the joints and ligaments of the spine. There are two subtypes of axSpA which represent the possible disease spectrum: ankylosing spondylitis (AS) and non-radiographic axSpA (nr-axSpA).[39] When the condition is found on X-ray, it is called AS, and when the condition can not be seen on X-ray but is found based on symptoms, blood tests, and other imaging tests, it is called nr-axSpA.[40] X-rays will not show evidence of nr-AxSpA because the inflammation has not yet caused visible damage to the sacroiliac joints. However, an MRI may indicate active inflammation in the soft tissues surrounding the joints.[41]

Ankylosing Spondylitis

Ankylosing spondylitis is a chronic, inflammatory disease primarily affecting the axial spine and can manifest with a range of clinical signs and symptoms which typically begin in early adulthood - the hallmark features include chronic back pain and progressive spinal stiffness, though it may also affect peripheral joints and digits.[42] AS often leads to impaired spinal mobility and can result in a hunched posture. In addition to skeletal involvement, AS can affect other body organs, manifesting in inflammatory bowel disease, acute anterior uveitis, and psoriasis, and is also linked to an increased risk of cardiovascular disease and pulmonary complication.[43] The exact cause of AS is unknown, but researchers believe that genetics play a role.[44] There is no cure for ankylosing spondylitis, but treatments can lessen symptoms and possibly slow progression of the disease. The goal of treatment is to ease pain and stiffness, prevent deformities, and maintain as normal a lifestyle as possible.[45]

Non-Radiographic Axial Spondyloarthritis

Non-radiographic axial spondyloarthritis is a recently described form of axial spondyloarthritis that has not caused substantial erosive damage to the sacroiliac joints, and in some patients it can evolve into AS. While AS has long been a recognised clinical entity due to the clear radiographic changes present in the sacroiliac joints, there is often a period where classic signs and symptoms of axSpa are present in the absence of radiographic changes in the sacroiliac joints. The identification of nr-axSpA has been made possible by advances in MRI technology, and a great deal of active research is being undertaken in classification, imaging, and therapy in nr-axSpA[46]

Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS), is a chronic inflammatory skin condition that causes painful, boil-like lumps that form under the skin which may cause skin abscesses and scarring. The symptoms of hidradenitis

[37] https://www.orpha.net/en/disease/detail/85438
[38] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3518441/
[39] https://www.arthritis.org/diseases/ankylosing-spondylitis
[40] https://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/symptoms-causes/syc-20354808
[41] https://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/symptoms-causes/syc-20354808
[42] https://www.ncbi.nlm.nih.gov/books/NBK470173/
[43] https://www.ncbi.nlm.nih.gov/books/NBK470173/
[44] https://www.hopkinsmedicine.org/health/conditions-and-diseases/ankylosing-spondylitis
[45] https://www.hopkinsmedicine.org/health/conditions-and-diseases/ankylosing-spondylitis
[46] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6514020/

suppurativa range from mild to severe. Lesions form because of blockages of the hair follicles, most commonly occurring in intertriginous areas and areas rich in apocrine glands such as the axillary, groin, perianal, perineal, and inframammary locations.[47]

Though the cause of HS is unknown, genetics, environment, and hormonal factors may play a role - HS is not infectious and is not linked to poor hygiene.[48] HS is thought to affect roughly 1 in 100 people, is more common in women than men, and typically starts around puberty, but may occur at any age after puberty. Environmental and behavioral factors also contribute - individuals with HS are more commonly overweight or obese, and smoking is also prevalent among those diagnosed with HS. Disease progression and severity are worse in patients who are overweight or who smoke.[49]

Because the early stages of hidradenitis suppurativa are often mistaken for other conditions, the average delay in the correct diagnosis is seven years.[50] Treatment varies based on severity and can include topical and systemic antibiotics, hormone therapy, immune modulators, and surgery.[51]

Utilizer Profile

Utilization of Cosentyx has increased since the FDA approved the drug in 2015. According to Colorado's All Payer Claims Database (APCD), 1,128 individuals utilized Cosentyx in 2022. Additionally, data from the APCD indicates that patients who utilize Cosentyx are most commonly insured through commercial insurance (66.26% of patients), followed by Medicaid (22.14% of patients) and Medicare Advantage plans (11.60% of patients). APCD utilization estimates can be viewed as low estimates, since data for some self-insured commercial insurance plans (ERISA) and Medicare FFS enrollees, as well as uninsured individuals, is not included. See Appendix P for more information.

Table 2
Utilization of Cosentyx (All Lines of Business)

Drug Name	2018	2019	2020	2021	2022
Cosentyx	478	727	956	1,149	1,128

[47] https://www.ncbi.nlm.nih.gov/books/NBK534867/
[48] https://www.ncbi.nlm.nih.gov/books/NBK534867/
[49] https://www.ncbi.nlm.nih.gov/books/NBK534867/
[50] https://www.ncbi.nlm.nih.gov/books/NBK534867/
[51] https://www.ncbi.nlm.nih.gov/books/NBK534867/

Figure 1
Cosentyx Utilization by Payer Type

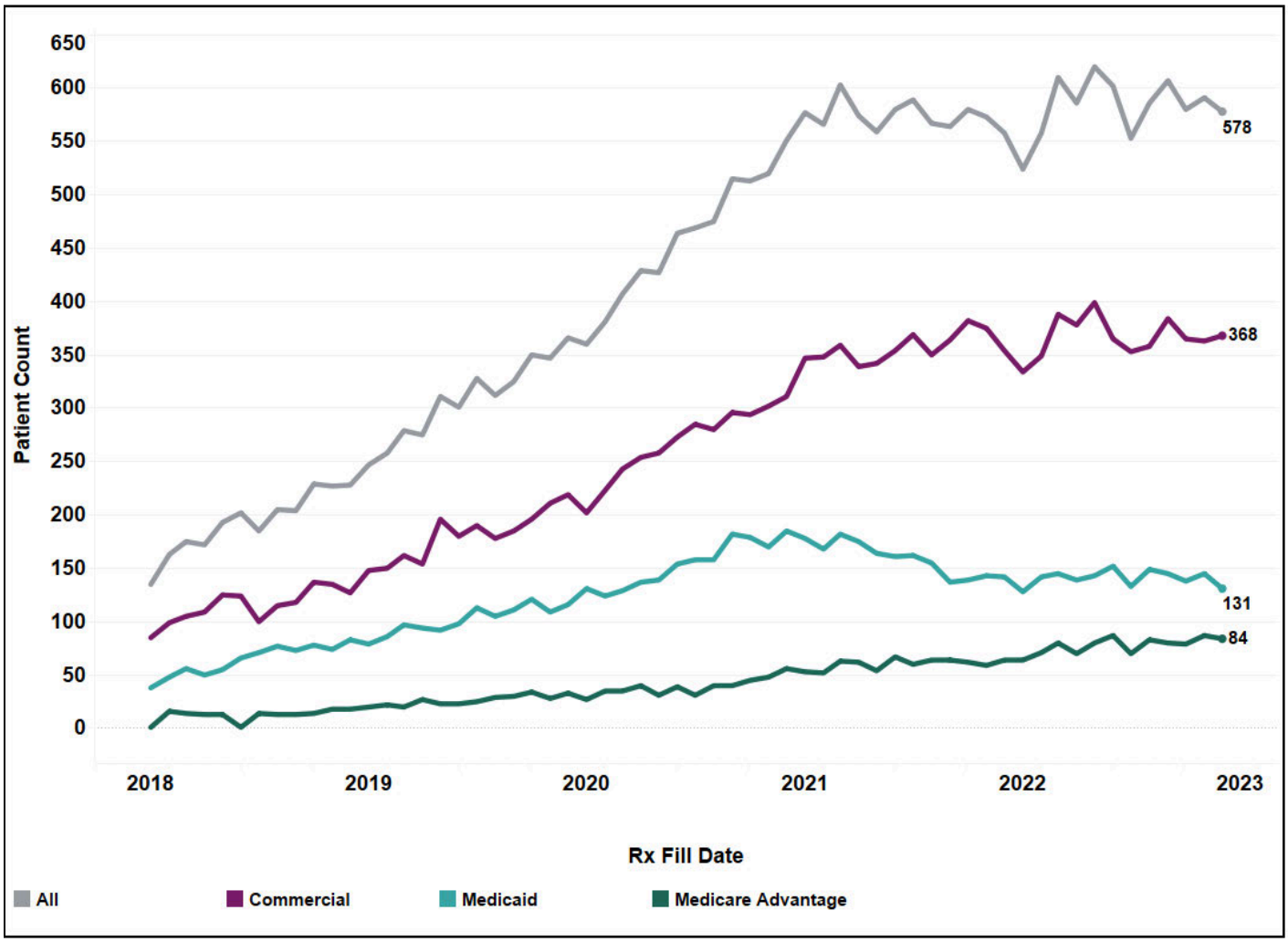


Figure 1 shows the number of patients who filled a prescription for Cosentyx each month between January 2018 and December 2022, where the purple line represents the number of commercially insured patients, the teal line shows the number of Medicaid patients, the green line shows the number of Medicare Advantage patients, and the gray line shows the total utilization in the Colorado APCD.

Figure 2
Insurance Information

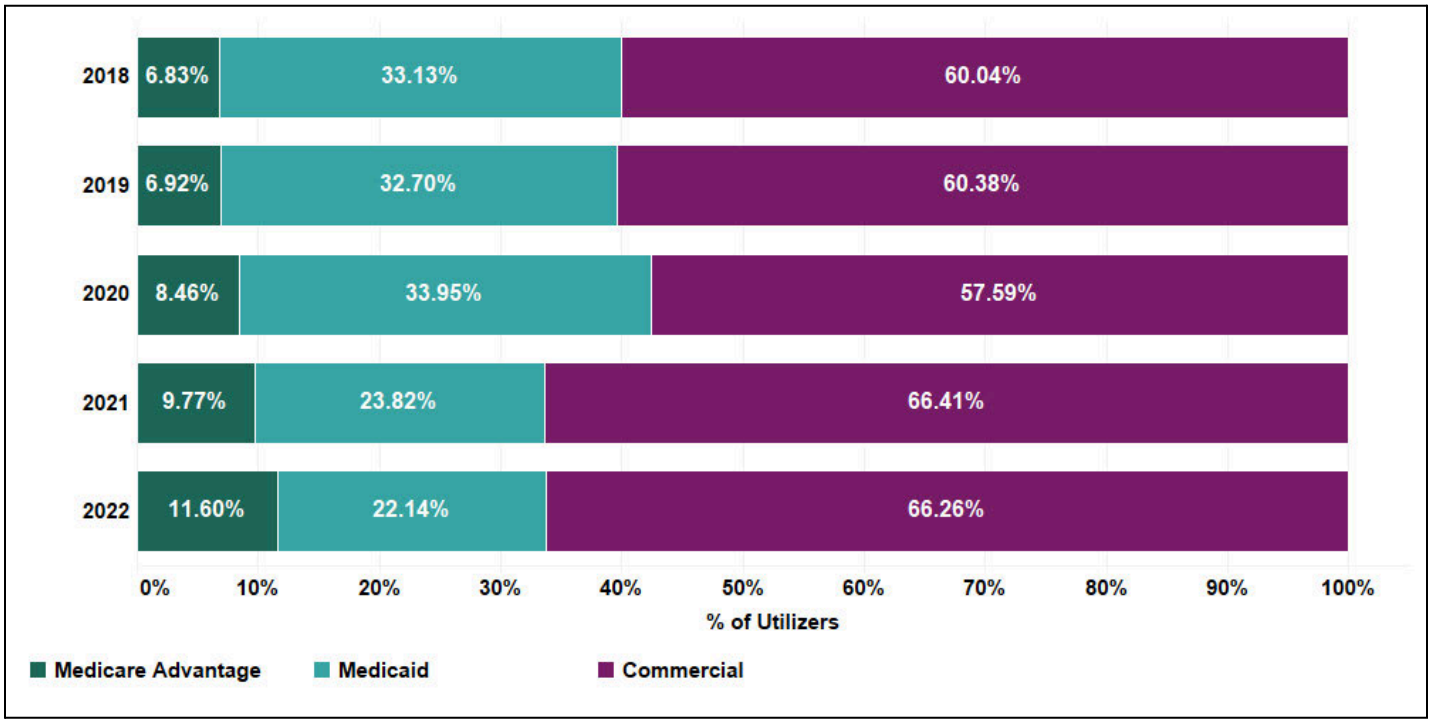


Figure 2 shows Cosentyx payer mix percentages from 2018 through 2022. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, teal represents patients with Medicaid, and purple represents patients with commercial insurance. From 2018 through 2022, between 57.59% and 66.41% of Cosentyx utilizers were commercially insured.

Health Equity Impact

Obtaining prescription drug-specific information regarding health equity can be a complex task. There is evidence that priority populations[52] experience health inequity associated with their use of medications, which causes an increased risk of adverse outcomes including mortality, morbidity burden, quality of life deficit, and patient safety issues.[53] Further, there may be condition- or disease-specific studies that investigate health inequities, but there are not always studies that investigate the impacts of a specific prescription drug. While there was not significant data regarding Cosentyx specifically, there was data regarding indications Cosentyx treats. Health equity literature reviews were conducted for five of Cosentyx's FDA-approved indications and are summarized in the table below. See Appendix L for more information.

[52] The Board's adopted definition of priority populations is: people experiencing homelessness; people involved with the criminal justice system; black people, indigenous people, and people of color; American Indians and Alaska natives; veterans; people who are lesbian, gay, bisexual, transgender, queer, or questioning; people of disproportionately affected sexual orientations, gender identities, or sex assigned at birth; people who have AIDS or HIV; older adults; children and families; and people with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities; and other populations as deemed appropriate by the Prescription Drug Affordability Board. 3 CCR 702-9, 1.1.C.

[53] https://pubmed.ncbi.nlm.nih.gov/36961038/

Table 3

Cosentyx Health Equity Literature Review Highlights by Indication

Indication	Health Equity Literature Review Highlights
PsO	• Hispanic and Black patients with psoriasis experienced more provider-related bias, stereotyping, misdiagnosis, and delayed diagnosis compared with white patients. Additionally, people with skin of color are underrepresented in clinical trials of psoriasis therapies. • Children with psoriasis are at approximately 20% to ~30% higher risk of developing psychiatric disorders, such as depression and anxiety, than children without any psoriasis diagnosis.
PsA	• One study found that white patients were five times more likely to be diagnosed with psoriatic arthritis compared with Black patients. The disparity in prevalence could potentially be due to underdiagnosis in historically marginalized racial/ethnic groups. • One study reported a significantly higher degree of disease severity and lower use of biologics among Black patients compared with white patients. One study found Black patients were 70% less likely to receive biologics than white patients.
JIA subsets: PsA and ERA	• Studies in the US have shown that within the first year of diagnosis, children of color and those with lower household income have higher disease activity as well as a longer "time to first appointment"
AxSpa subsets: AS and nr-axSpa	• AxSpa is historically considered a disease predominantly impacting men and it is often under-recognized or misdiagnosed in women. • Multiple researchers have raised concerns about detection bias with regard to diagnosing axSpa among people of color. Despite being diagnosed at lower rates than white and Hispanic patients, Black patients reported greater discomfort and impairment, had higher levels of inflammation, and showed more joint damage and deterioration on X-rays and MRIs.
HS	• People of color, particularly Black Americans, experience a significantly higher burden of the disease. • Disparities also include delay in diagnosis, access to specialized care, and underrepresentation in clinical trials

During the selection of eligible prescription drugs for affordability reviews, the Board reviewed a Social Vulnerability Index Score (SVI) for all eligible prescription drugs. The SVI score represents the percent of individuals who use Cosentyx who live in a county with a score above the Colorado average score. Individuals residing in counties with SVI scores higher than the statewide average may be more vulnerable to adverse outcomes due to social conditions in their county. The SVI score measurement is not meant to be a comprehensive assessment of Cosentyx and health equity. Rather, it is meant to be a contextual snapshot to better understand if the typical patient who uses Cosentyx lives in a county that has a higher vulnerability to adverse outcomes due to social conditions than the average Colorado county.

In 2022, 56.82% of patients taking Cosentyx lived in a county with a higher SVI score than the statewide average. This means that patients taking Cosentyx have a slightly lower likelihood of living in a county with higher vulnerability to adverse outcomes due to social conditions than the average Coloradan. See Appendix L for more information.

Figure 3
Map of Colorado by 2022 SVI Score for Utilizers of Cosentyx

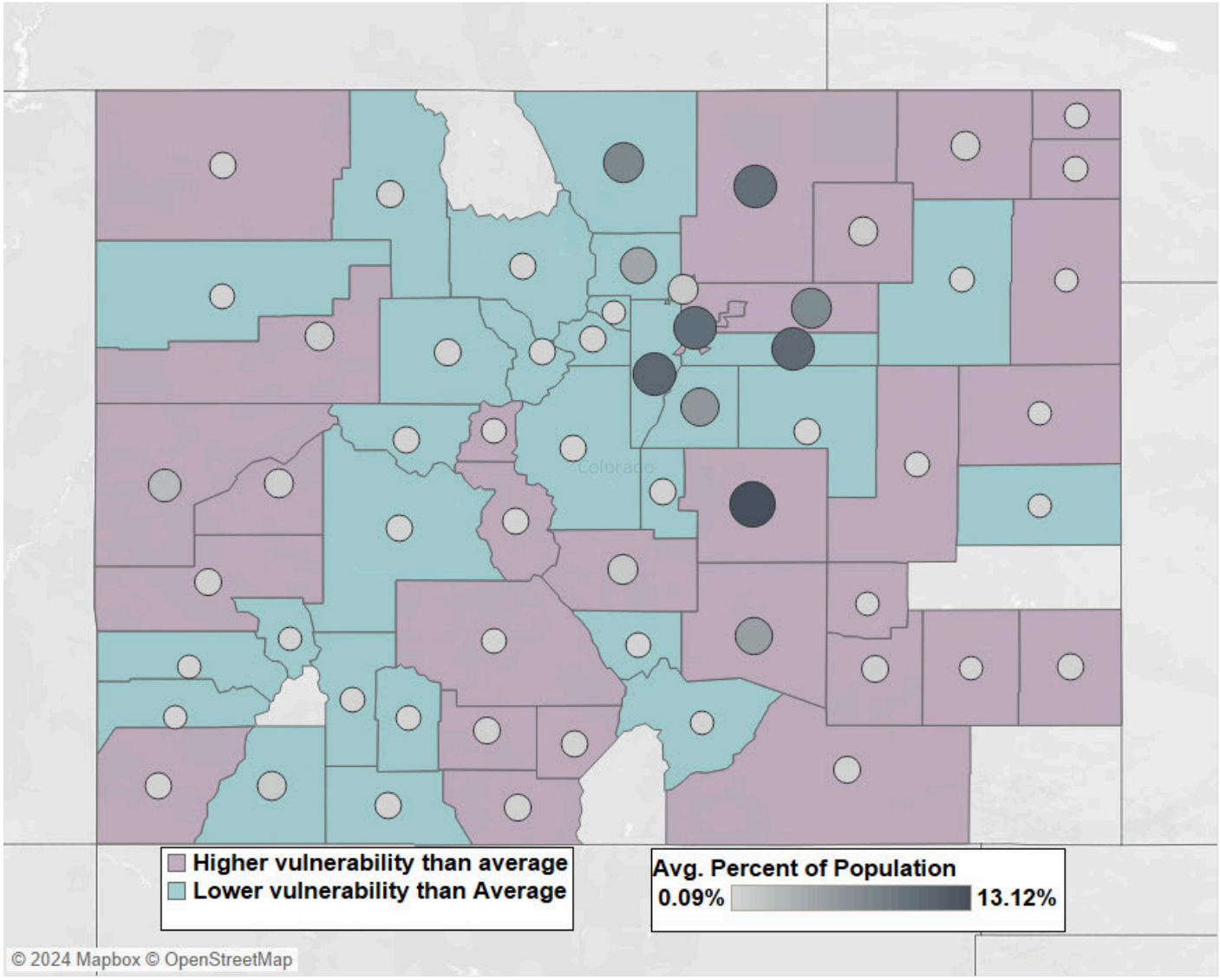


Figure 3 shows a map of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than average SVI score. Counties without color did not have any patients who used Cosentyx in 2022 residing in them. The dots on each county show the percent of patients who used Cosentyx in 2022 by county where a larger, darker dot represents a higher portion of utilizers and smaller, lighter dots represent a smaller portion of the population.

Board staff received patient and caregiver input through an online survey aimed at gathering information regarding the health and financial effects of Cosentyx. Survey participants could voluntarily provide information regarding whether they were a member of a priority population. Of the 15 national respondents, seven were members of a priority population, and of the five Colorado respondents, two were members of a priority population.

Therapeutic Alternatives

The Board adopted a definition of therapeutic alternatives as prescription drugs in the same pharmacological or therapeutic class that have been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or prescription drugs recommended as consistent with standard medical

practice by medical professional association guidelines (3 CCR 702-9, Part 1.1.C). For the purposes of this affordability review, therapeutic alternatives were identified through the review of medical professional association guidelines. The resulting in-class therapeutic alternatives are summarized in Table 4 below. Information related to Cosentyx's therapeutic alternatives is contained throughout this summary report and appendices.

Table 4
Cosentyx Therapeutic Alternatives Details

Non-Proprietary Name	Brand Name	Mechanism of Action	Approved Indication(s) (FDA Approval Date)
bimkizumab-bkzx	Bimzelx	IL-17A/17F inhibitor	10/17/23 PsO in adults only
tildrakizumab-asmn	Ilumya	IL-23 inhibitor	3/20/2018 PsO in adults only
brodalumab	Siliq	IL-17 inhibitor	2/15/2017 PsO in adults only
risankizumab-rzaa	Skyrizi	IL-23 inhibitor	4/23/2019 PsO in adults only 1/21/2022 PsA in adults only
ustekinumab	Stelara	IL-12/IL-23 inhibitor	9/25/2009 PsO adult and pediatric 9/20/2013 PsA adult and pediatric
ixekizumab	Taltz	IL-17A inhibitor	3/22/2016 PsO in adults 3/26/2020 PsO in pediatric 12/1/2017 PsA in adults only 8/23/2019 AS 5/29/2020 nr-axSpA
guselkumab	Tremfya	IL-23 inhibitor	7/13/2017 PsO in adults only 7/13/2020 PsA in adults only

Table 4 shows details of Cosentyx's therapeutic alternatives and FDA approval dates.[54]

Utilization information for Cosentyx and therapeutic alternatives is outlined below.

Table 5
Utilization of Cosentyx and identified Therapeutic Alternatives

Brand Name	2018	2019	2020	2021	2022
Cosentyx	478	727	956	1,149	1,128
Ilumya		*	*	16	31
Skyrizi				459	1,028
Stelara	683	895	1,092	1,479	1,700
Taltz	155	274	418	971	1,140
Tremfya	69	122	171	300	445

Table 5 shows the number of utilizers of Cosentyx and therapeutic alternatives by year from 2018 - 2022.

[54] Some figures and tables in the summary report and appendices may not include information for Bimzelx and Ilumya due to low utilization as reported in the APCD.
[55] Only therapeutic alternatives with utilization in the APCD are presented here. Other therapeutic alternatives presented in Table 4, specifically Bimzelx, were too recently approved by the FDA to have utilization in the APCD.

Figure 4

Insurance information for Therapeutic Alternatives

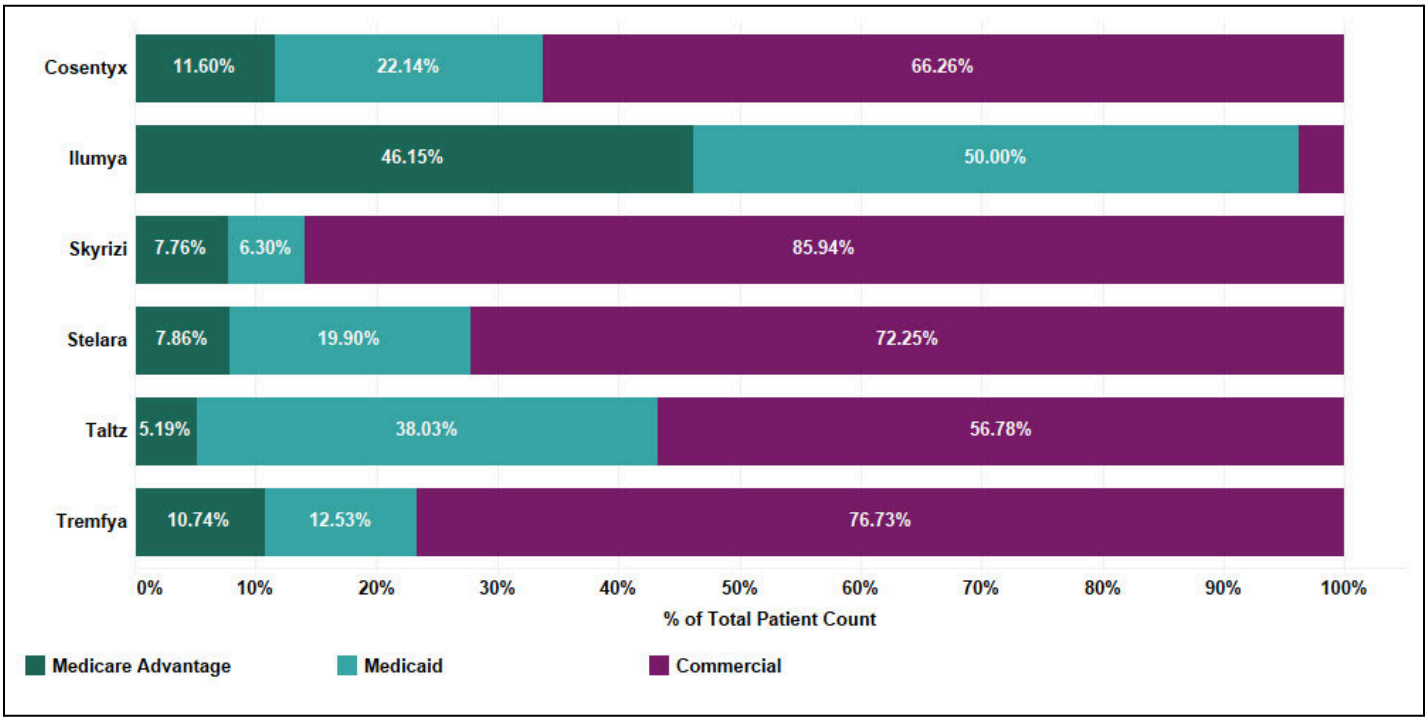


Figure 4 shows the 2022 payer mix for Cosentyx and its identified therapeutic alternatives. This figure shows the percent of patients by payer type and year where green represents patients with Medicare Advantage, teal represents patients with Medicaid, and purple represents patients with commercial insurance. Cosentyx had 66.26% of patients covered by commercial insurance, which was higher than two and lower than three of the identified therapeutic alternatives.

Cosentyx Price and Cost Profile

The Price and Cost Profile includes information on what different entities on the prescription drug supply chain charge for Cosentyx, as well as what different entities pay for Cosentyx. This profile also contains information on Cosentyx's financial effects on health, medical, and social service costs. Affordability review components present in this profile include information from Appendices A, B, D, E, H, I, J, K, and O.

Table 6

Cosentyx's 2022 Price & Cost per Person Statistics

Price & Cost Per Person Statistics	Amount
Average WAC per Course of Treatment per Person[56]	[redacted]
Average Paid per Person	$46,948
APPY - Plan Paid	$44,963
APPY - Out-of-Pocket[57]	$3,297

[56] Course of treatment is calculated based on utilization not FDA labeling recommended doses. For course of treatment methodology please see June 9th, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing. This estimate uses the January 2024 WAC per unit and 2022 (the most recent data available) utilization of Cosentyx in the APCD.

[57] Medicaid copayments are $0-$3 for each prescription fill, as a result, Medicaid out of pocket paid amounts are removed from all averages in the data presented below, however, it is included in the statewide totals when reviewing the total amount patients paid. Medicaid copay information: https://www.healthfirstcolorado.com/copay/

Table 7
Cosentyx's 2022 Statewide Price & Cost Statistics

Statewide Price and Cost Statistics	Amount
Total Paid Amount	$52,957,875
Total Plan Paid[58]	$50,717,952
Total Medicaid Paid	$13,018,318
Total Patient Paid	$2,197,945
Gross-to-net Estimates	[redacted]

The current WAC for Cosentyx is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in January of 2015. This is a 116.64% increase from January 2015 to January 2024, a 43.06% increase in the past five years, and a 7% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[59] See Appendix A for more information.

Pursuant to section 10-16-1405, C.R.S., carriers and pharmacy benefit managers submit data about the highest cost prescription drugs to the APCD, including the fifteen prescription drugs that caused the greatest increase to the carrier's premiums. Five of the nineteen carriers who submitted data reported Cosentyx in the top fifteen drugs that caused the greatest increase to premiums and one of these submitters reported Cosentyx as the fourth highest drug that caused the greatest increase to premiums. Additionally, prescription drug transparency data from other states indicates Cosentyx is among the costliest drugs in the state (Maine, Oregon). See Appendix O for more information.

[58] Total Plan Paid represents the amount paid by a patient's primary insurance coverage, even though secondary coverage may have paid an amount. Secondary insurance coverage paid amounts are generally captured in Total Paid Amounts.
[59] Course of Treatment methodology outlined in Board Staff Memo from June 6, 2023: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing.

Figure 5
Payer Rank of Cosentyx Impact on Premiums in 2022

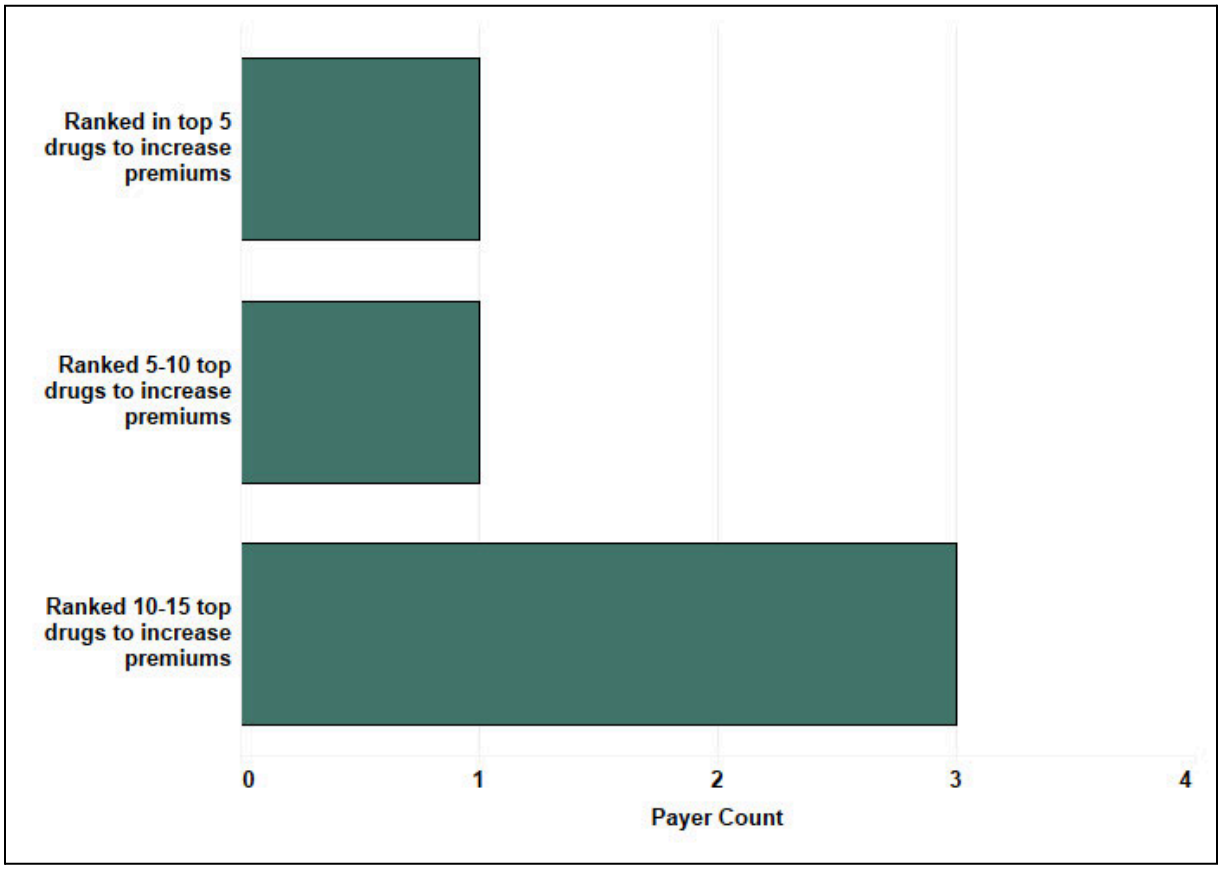


Figure 5 shows the number of payers that ranked Cosentyx in the top 15 prescription drugs that increased premiums.

Payers and Pharmacy Benefit Management Firms were required to identify in their submission which 15 drugs caused the highest increases to premiums, however, no additional information was required pursuant to section 10-16-1405(1)(a)(IV), C.R.S. As a result, the specific dollar impact Cosentyx had on premiums, or even how its rank compared to other prescription drug premium impacts, is unknown.

While this information can be insightful in understanding Cosentyx's impact on a broader portion of the health care system, Board staff do not recommend the Board heavily weigh this information this year. Per section 10-16-1405, C.R.S., only the top drugs are submitted for each reference, and more data and research would be necessary to understand the actual impacts to premiums and relative impact of each drug for each carrier.

The SEC requires that foreign public companies file a Form 20-F each year. This form provides a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Novartis' 2023 20-F details that global net sales of Cosentyx reached $4.980 billion in 2023, a 4% increase from $4.788 billion in 2022 (p.46).[60] Additional information on estimates of Cosentyx's share of Novartis' total sales is contained in Appendix K. See Appendix O for more information.

Out-of-Pocket Estimates

Patient copayment and other cost sharing depends on many factors, including: a patient's insurance coverage, how much has already been contributed to out-of-pocket maximum amounts in a benefit year, and

[60] https://www.sec.gov/Archives/edgar/data/1114448/000137036824000004/nvs-20231231.htm

whether the patient receives other assistance to pay for their portion of prescription drug. The APCD provides data on the patient portion of the claim paid for the drug, but does not contain any information on assistance programs. Patients, caregivers, and individuals with scientific or medical training provided input regarding their experiences with assistance programs through public meetings, surveys, and voluntarily submitted information. See Appendices H, I, and J for more information.

The average annual out-of-pocket cost per person per year for individuals with commercial insurance is $2,801. There was wide variation in monthly average out-of-pocket costs, where 57.25% of individuals paid a total amount between $0-$50, though some individuals paid as much as $12,100 - $12,150.[61] Figure 6 outlines the annual out-of-pocket amounts for commercially insured individuals by type of out-of-pocket expense. See Appendix E for more details.

Figure 6

Average Commercial Out-of-Pocket Cost Comparison[62]

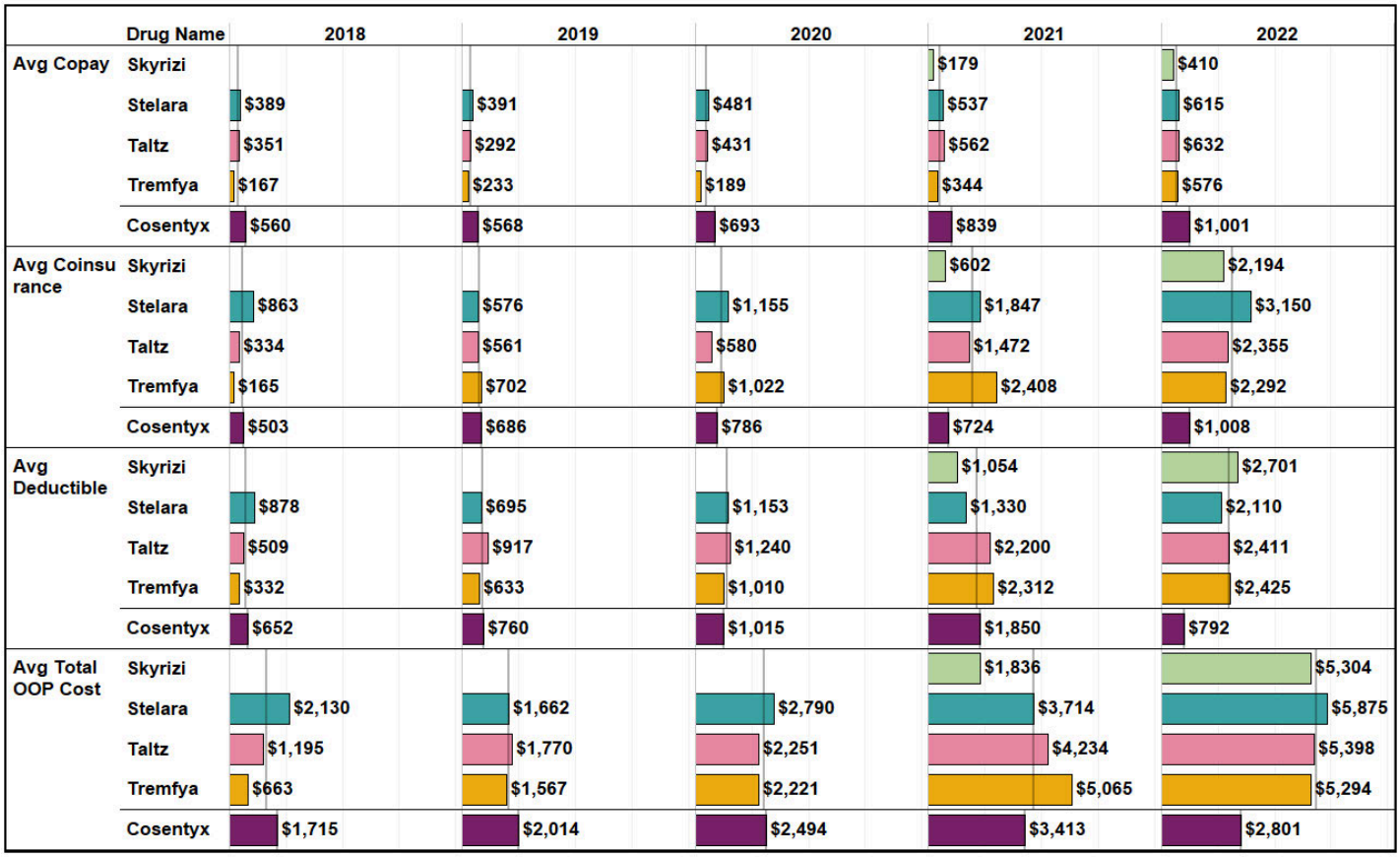


Figure 6 shows each out-of-pocket cost type for commercially insured individuals with Cosentyx in dark purple and its therapeutic alternatives by year. There is a light gray line that shows the average of the therapeutic alternatives as a comparison to determine if Cosentyx is more or less expensive than the average of its therapeutic alternatives. For example, the bottom right corner shows the average total out-of-pocket cost in 2022: Cosentyx was $2,801, which is lower than all of the identified therapeutic alternatives, while the average across all therapeutic alternatives is $5,468.

Another snapshot of out-of-pocket costs for individuals with commercial insurance is summarized below for both Cosentyx and identified therapeutic alternatives.

[61] For the vast majority of patients covered by Medicaid, patient prescription drug copayments are between $0-$3 for each prescription drug fill and most individuals with Medicaid coverage do not have deductibles or coinsurance. See Appendix E for more information.

[62] Ilumya and Siliq are identified therapeutic alternatives with very low utilization in the APCD (i.e., utilization was less than 30 patients in 2022); where appropriate, they have been removed as comparators due to this low utilization.

Table 8

Average Monthly Commercial Out-of-Pocket Cost Information in 2022

	Cosentyx	Ilumya	Skyrizi	Stelara	Taltz	Tremfya
Average Total OOP Cost	**$257.58**	$175.46	$467.29	$489.92	$235.91	$487.70
Average Coinsurance Amount	**$92.08**	$0.00	$199.55	$272.88	$109.75	$218.11
Average Copay Amount	**$91.91**	$175.46	$37.02	$54.91	$29.26	$54.59
Average Deductible Amount	**$73.59**	$0.00	$230.73	$162.14	$96.90	$215.00
Average Days Supply	**31.3**	83.3	60.5	52.6	30.0	46.2

Table 8 shows average monthly out of pocket expenditures for individuals who are commercially insured.

In 2022, in an average month, an individual with commercial insurance paid a total of $257.58 for Cosentyx: $73.59 went towards a patient's deductible, $92.08 was paid towards coinsurance, and $91.91 was paid via copayment. Similar information is provided for therapeutic alternatives. These averages are calculated based on claims from the APCD, which does not include information about assistance programs that individuals might use when filling their prescriptions.

Figure 7

Changes in Copay amounts by Year and Drug 2018-2022

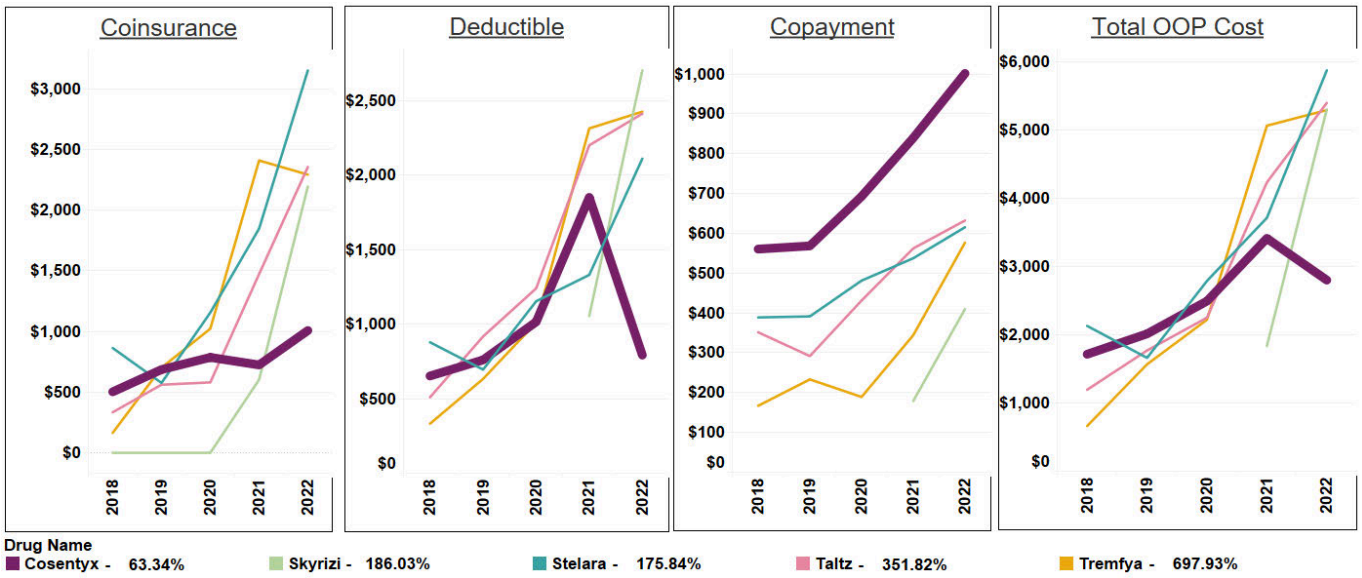


Figure 7 shows the annual change in the annual average out-of-pocket amounts comparing Cosentyx (dark purple) to its therapeutic alternatives. Below the graph, the percent change in total out-of-pocket costs from January 2018-December 2022 for each drug is indicated. Cosentyx had the lowest total out-of-pocket cost and the lowest increase in total out-of-pocket costs with a 63.34% increase. See Appendix E for more information.

Novartis voluntarily submitted the following information regarding patient assistance programs: "Novartis has a co-pay assistance program in the US that helps thousands of patients with commercial health coverage access our medicines at reduced cost to them. In 2022, 74% of Colorado patients accessing Cosentyx through their commercial coverage used a Cosentyx copay card. So far in 2023, 72% of these patients have used a Cosentyx copay card. Of these patients, 90% paid $0 out-of-pocket for Cosentyx. The remainder paid a nominal amount."

The manufacturer also identified additional assistance programs, including Novartis' Covered Until You're Covered Program, which is available for eligible patients who have commercial insurance, a valid prescription for Cosentyx, and a denial of insurance coverage based on a prior authorization request. The program provides Cosentyx for free to eligible patients for up to two years, or until they receive insurance coverage approval, whichever occurs first. Novartis confidentially submitted: [redacted] See Appendices J and K for more information.

Board staff received information in surveys that of five Colorado respondents, four indicated they utilize patient assistance programs, and one respondent reported they have difficulty affording Cosentyx despite using a patient assistance program. See Appendices H, I, J, and K for more information.

Rebates, Discounts, and Price Concessions Estimates

The gross-to-net sales estimate is a proprietary estimate where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, assistance programs, and other price concessions, compared to gross sales to get a percentage estimate of all discounts.[63] The gross-to-net sales estimate was [redacted] in the first quarter of 2016, which increased to [redacted] in the fourth quarter of 2023. Additionally, In 2021, 6 of 25 carriers reported to the APCD that Cosentyx was in the top 15 drugs for which the carrier received the largest rebate. See Appendix K for more information.

[63] All gross-to-net estimates are provided on a four quarter moving average.

Figure 8
Estimated Total Gross-to-Net Sales

Figure 8 shows the total gross-to-net sales estimate for Cosentyx and identified therapeutic alternatives. The gross-to-net sales estimate for Cosentyx has increased to [redacted] in the fourth quarter of 2023, [redacted]

Cosentyx's Health and Financial Effects

One component of affordability reviews is an assessment of the relative financial effects on health, medical, or social service costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. Information regarding Cosentyx's relative financial effects on health, medical, or social service costs is summarized here from literature reviews (Appendix D), input from patients and caregivers (Appendix H), input from individuals with scientific and medical training (Appendix I), and voluntarily submitted information (Appendix J). These summaries are structured to focus first on Cosentyx's health effects, followed by financial effects.

64 [redacted]

Cosentyx's Health Effects

The FDA label provides information on Cosentyx's impact on the health effects on the indications it is approved to treat. See Appendix D for more information. Patients, caregivers, and individuals with scientific and medical training reported in meetings and surveys regarding health effects. Examples of feedback, including quotes that summarize common themes, are provided below; see Appendix H and Appendix I for more information.

- Cosentyx has reduced pain and fatigue, increased mobility, and improved overall symptoms and quality of life in the majority of survey respondents of all indications. However, some participants indicated no improvement from taking Cosentyx.
- The most commonly reported side effects were increased susceptibility to infections and decreased immune strength. Seven out of 15 of the participants said they did not experience any side effects from Cosentyx.

Additionally, patients and caregivers provided input regarding therapeutic alternatives. Select answers are summarized below; see Appendix H for more information.

- All survey respondents reported having tried at least one other prescription drug to treat their condition, the majority of which had cycled through another medication before being prescribed Cosentyx. The most common reasons participants gave for cycling through therapeutic alternatives were adverse side effects, limited efficacy, and the medication stopped working.

In addition to gathering information from patients, caregivers, and individuals with scientific and medical training, Board staff conducted literature reviews to compile evidence of the clinical effectiveness of Cosentyx. To do this, Board staff examined studies conducted by Health Technology Assessment (HTAs) organizations. HTA organizations, often found within or supporting governmental agencies in other countries, provide evaluations of both clinical and cost effectiveness of prescription drugs. HTAs can provide consistent and thorough assessments of a prescription drug' clinical effectiveness. See Appendix D for information compiled from six HTA organizations for Cosentyx's FDA-approved indications.

Cosentyx's Financial Effects

Understanding a prescription drug's financial effects on health, medical, and social service costs as compared to therapeutic alternatives can be a complex task. HTA organizations conduct evaluations of the effects and impacts of a prescription drug, which may address the direct, intended consequences as well as their indirect, unintended consequences. Though nearly all HTA organizations take into account patient, caregiver, and provider perspectives when determining a prescription drug's cost effectiveness, Board staff were able to gather direct input from those groups on Cosentyx's financial effects on health, medical, and social service costs.

Patients, caregivers, and individuals with scientific and medical training were asked in public meetings and in surveys to share any additional information about how Cosentyx affects them financially. Participants and respondents shared experiences related to out-of-pocket costs, assistance programs, and utilization management requirements. Select answers are highlighted below; see Appendix H for more information.

- The most common themes from survey responses and meeting attendees were that Cosentyx reduced the amount of time and money spent on going to the doctor, hospital, or needing surgery, and has allowed them to work to support their family.
- Some patients reported cutting costs in other areas to pay for their medication.
- Of four of five Colorado respondents who utilize patient assistance programs, one respondent reported they have difficulty affording Cosentyx despite using a patient assistance program.
- Some patients discussed difficulty with household tasks, taking sick leave for treatment, and the administrative burden required to maintain their medication.

Board staff conducted literature reviews to compile evidence of the cost effectiveness of Cosentyx. A summary of these organizations, the country where they are found, and their conclusions regarding the clinical effectiveness of Cosentyx are outlined in Appendix D.

Cosentyx Access to Care Profile

The Access to Care Profile examines potential access to care concerns related to Cosentyx and whether there is evidence that the causes of access to care concerns may be related to Cosentyx's price or cost. This profile includes an examination of potential relationships of changes between utilization, price, and costs as well as information on safety net providers, utilization management requirements, and health benefit plan design.

Price Effect on Access

Cosentyx's WAC has increased 13 times since it was approved by the FDA in January 2015, increasing a total of 116.64% since introduction, an increase that is higher than inflation (Figure 9 below). See Appendix A for more information. From 2018 to 2022, APCD data shows increases in Cosentyx's average annual patient out-of-pocket costs and total patient paid amounts, and a 71.99% increase in average annual out-of-pocket costs (Table 9 below). See Appendix E for more information. Meanwhile, APCD data shows monthly increases in average utilization of Cosentyx (See Figure 10 and Table 9 below).

Cosentyx is a biologic drug that does not have any patent data in the FDA purple book[65] or in the I-MAK database[66], so all patent information is from Novartis' latest SEC 20-F filing from January 31, 2024: "Cosentyx. US: Five patents on composition of matter (2025 (4), 2026), PTE (2029); patent on psoriatic arthritis use (2031); patent on psoriasis use (2032); two patents on ankylosing spondylitis use (2032, 2033)".[67]

There is no biosimilar competition for Cosentyx and the latest patent described in the 20-F filing is set to expire in 2033. Evaluating patents and other sources of exclusivity can be helpful in understanding potential access concerns, because there is evidence that such market conditions are associated with increased drug prices, limited availability, and increased costs to consumers and payers.[68]

Table 9

Annual Utilization and Expenditures

	2018	2019	2020	2021	2022
Patient Count	478	727	956	1,149	1,128
Total Paid	$17,496,392	$29,831,351	$43,762,979	$51,499,809	$52,957,875
Average Paid Per Person	$36,603	$41,033	$45,777	$44,821	$46,948
Total Patient Paid	$505,537	$903,303	$1,442,560	$2,721,858	$2,197,945
Average OOP Cost	$1,917	$2,113	$3,024	$4,048	$3,297
WAC per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[65] FDA Purple Book: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or

[66] I-MAK's 'The Drug Patent Book' https://drugpatentbook.i-mak.org/.

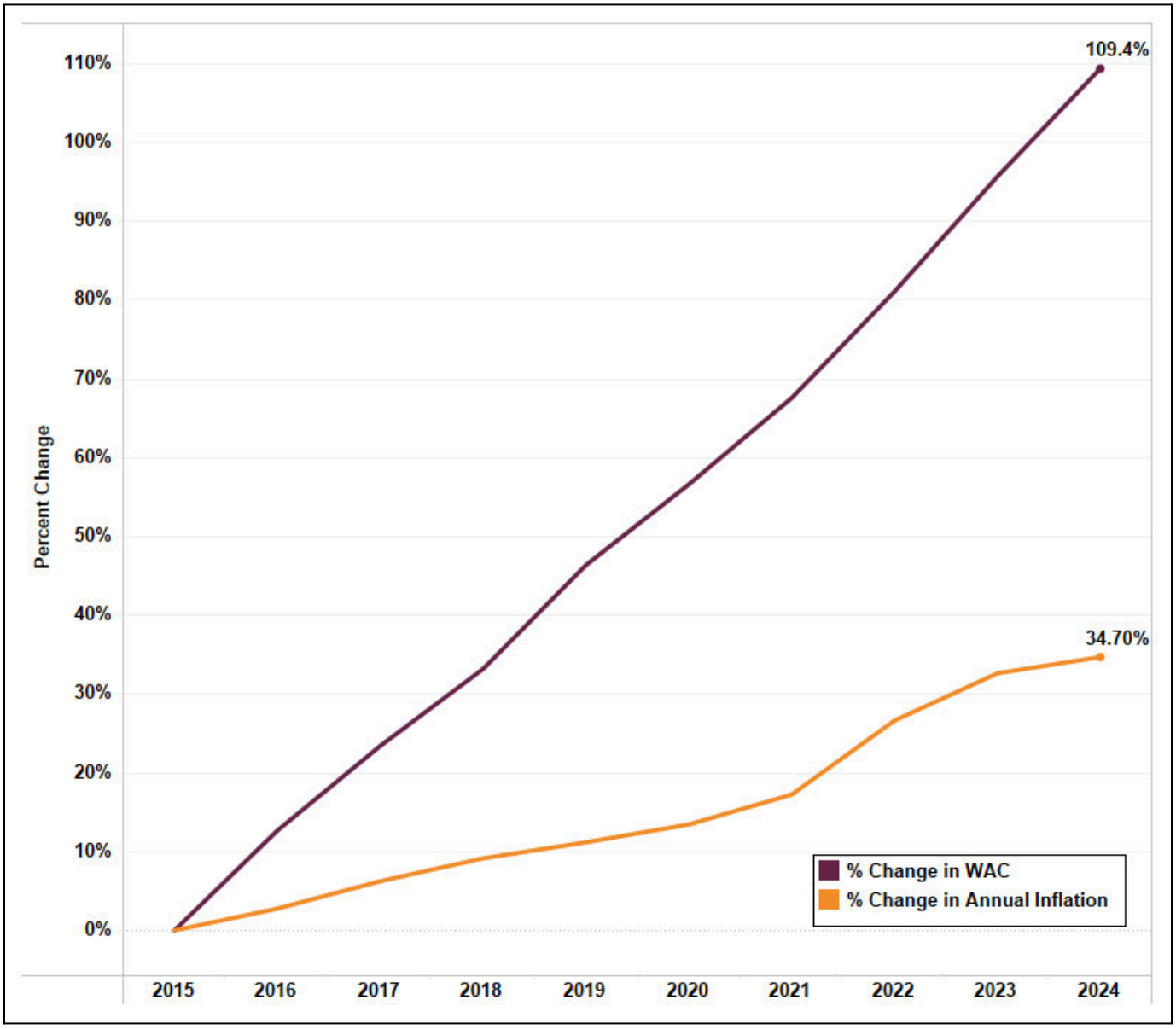
[67] https://www.sec.gov/Archives/edgar/data/1114448/000137036824000004/nvs-20231231.htm

[68] https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00826-4

Table 9 shows the year-over-year increases in the number of patients using Cosentyx, the total amount paid for Cosentyx, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

Figure 9

Percentage Change in WAC (Cosentyx) Compared to Annual Inflation



For additional context, Figure 9 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.

Figure 10

Monthly Utilizers for Cosentyx and Therapeutic Alternatives

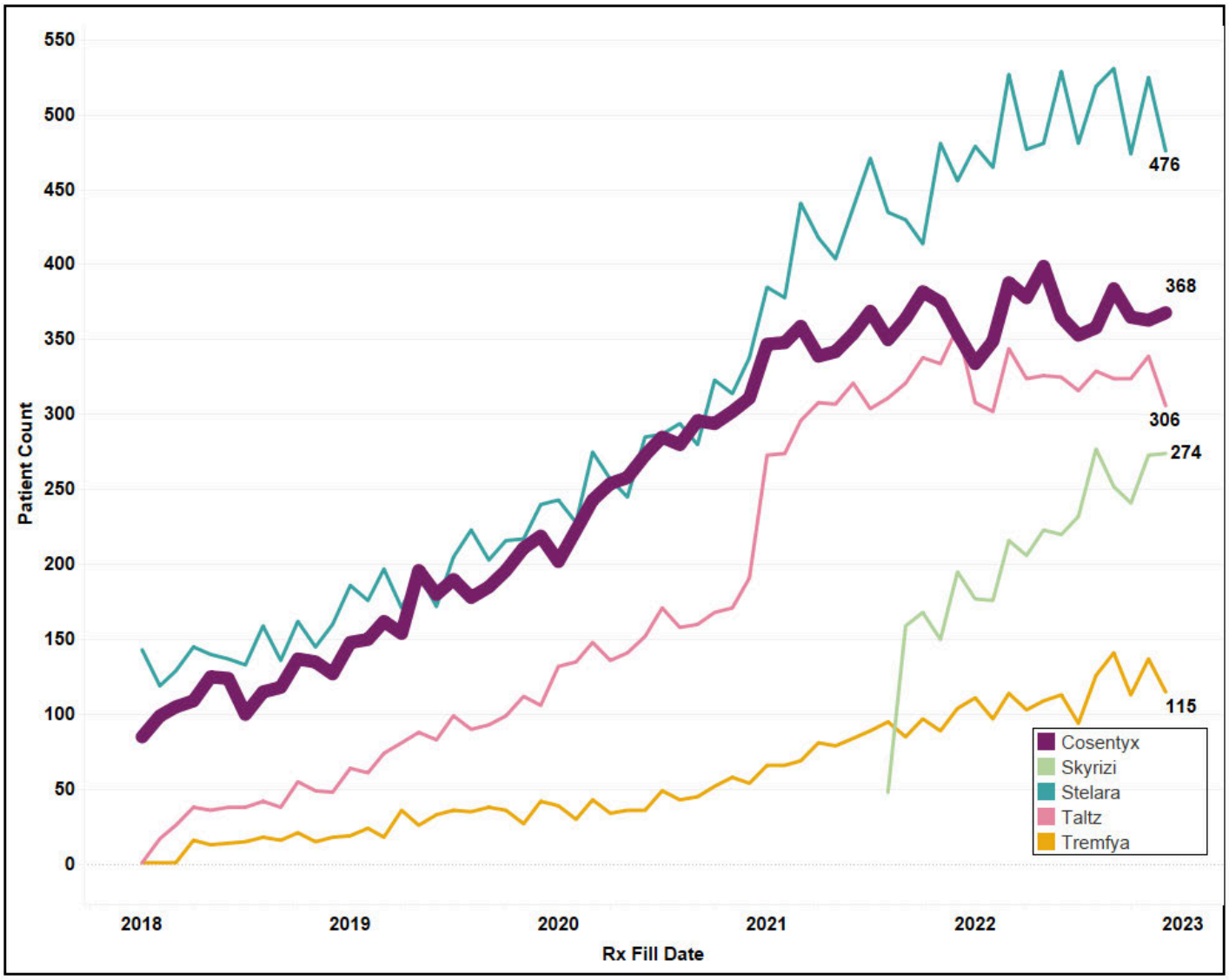


Figure 10 shows the monthly number of commercially insured utilizers of Cosentyx and therapeutic alternatives. Utilization of Cosentyx has increased from January 2018 to December 2022 and it is the second highest utilized drug when compared to its therapeutic alternatives.

Figure 11
Monthly Total Paid and Average Total Paid (All Lines of Business)

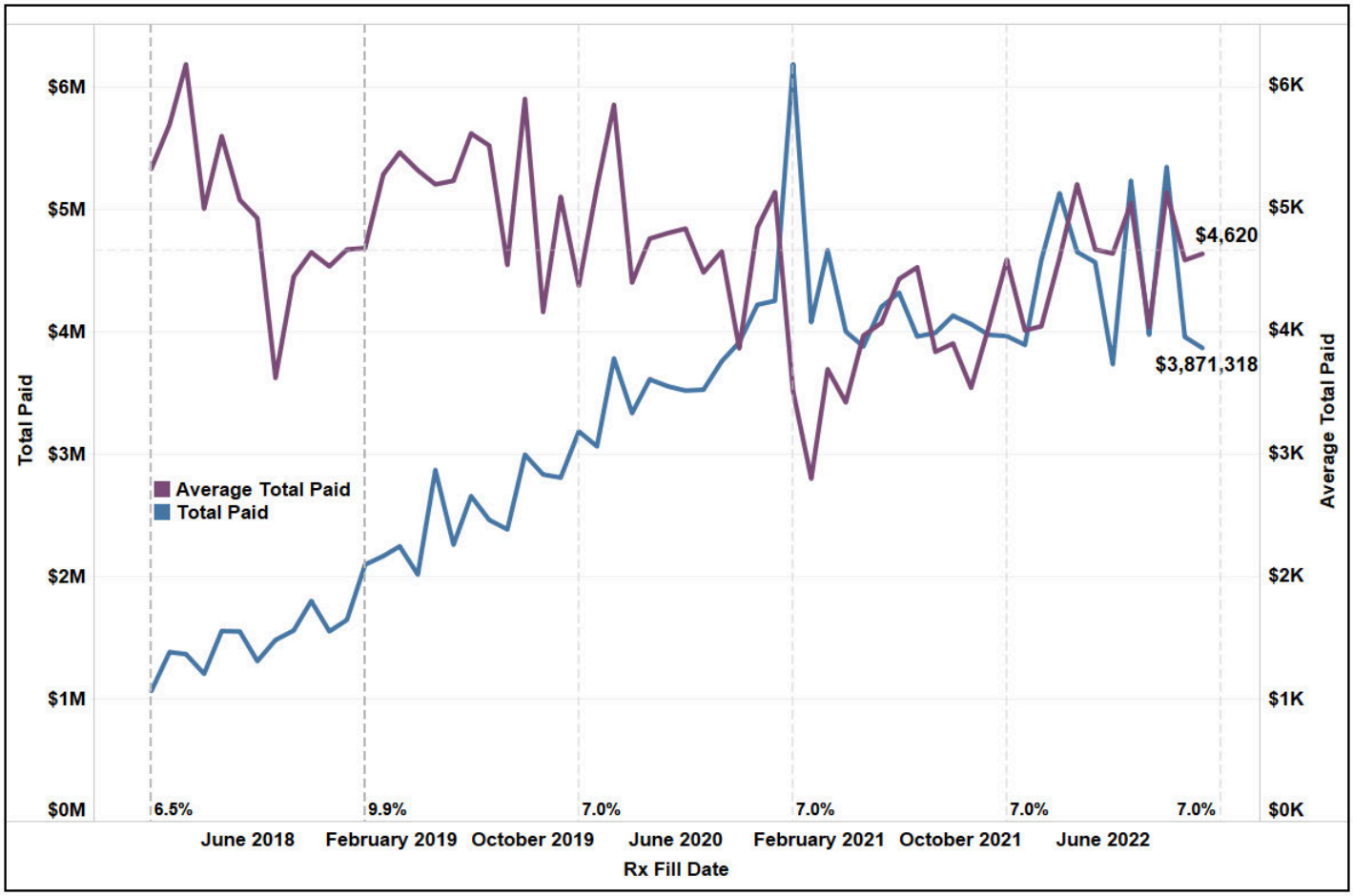


Figure 11 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical dotted lines representing when there were increases in WAC with the magnitude of the increase written to the right of the line. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Cosentyx increased from 478 in 2018 to 1,128 in 2022.

Safety Net Providers, Utilization Management Requirements, and Health Benefit Plan Design

Individuals with scientific and medical training provided input that safety net providers participate as covered entities in the federal 340B Drug Pricing Program administered by the U.S. Health Resources & Services Administration (HRSA) and dispense Cosentyx. See Appendix H for more information. No safety net providers volunteered information regarding Cosentyx's utilization in a safety net setting, nor the nature of the 340B discount for Cosentyx. See Appendices F, I, and M for more information.

It is difficult to precisely know how many uninsured patients in Colorado have an indication treated by Cosentyx. Patients and caregivers who responded to the survey provided some insight. See Appendix H for more information.

Utilization management requirements, along with prescription drug formularies, are meant to encourage the use of medically appropriate and cost-effective drug-related products that meet the needs of patient

populations.[69] To better understand health benefit plan design coverage and formulary structure, data was accessed by Colorado Division of Insurance (DOI) staff for the affordability review. Data pulled was for carriers in the individual and small group markets for which DOI receives annual rate filings. As such, this data does not describe the entire insurance market in Colorado, but can shed valuable information on benefit plan design and out-of-pocket costs.

Six of ten commercial carriers in the Colorado market cover Cosentyx. Three carriers that cover Cosentyx require prior authorization, two carriers require prior authorization and step therapy, and one carrier covers Cosentyx with unrestricted access. In total, 289 plans provide coverage for Cosentyx. In general, the majority of carriers place Cosentyx on the middle to highest formulary tiers, meaning a higher portion of the drug is paid by patients than drugs on lower tiers until the out-of-pocket amount under the plan is paid by the insured.

[69] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10398227/

Appendix A

Cosentyx: Wholesale Acquisition Cost

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the wholesale acquisition cost of the drug. (C.R.S. § 10-16-1406(4)(a)).

Rule: The Board will consider both the current wholesale acquisition cost of the prescription drug and changes in the prescription drug's wholesale acquisition cost over time. (3 CCR 702-9, Part 3.1.E.2.a).

Policy: Information regarding the initial WAC, the current WAC, and changes to WAC over time. (PDAB Policy 04, p. 6).

Underlying Methodology: Board staff compiled WAC data for Cosentyx for the Board's consideration in the following manner:

1. Using AnalySource, staff pulled all effective WAC per unit amounts and dates associated with the drug.
2. Staff calculated the percent change in WAC since launch and in past five years by using the following calculation:
   (Current WAC - Initial WAC) / Initial WAC
3. Staff calculated annual inflation amounts by identifying the Bureau of Labor Statistics' (BLS) Annual Inflation Numbers using the Denver-Aurora-Lakewood area to compare WAC changes over time to inflation.[1]

Data Source(s):

- AnalySource's WAC amount, representing the manufacturer's published catalog or list price for a drug product to wholesalers as reported to First Databank by the manufacturer.
- U.S. Bureau of Labor Statistics for Denver-Aurora-Lakewood for annual inflation numbers.

Considerations and Data Limitations:

- Precise WAC amounts are confidential and may only be shared with the Board, Board staff, and Board contractors.
- The WAC does not consider rebates, discounts, or actual paid amounts.

Cosentyx: Wholesale Acquisition Cost Evidence

The current WAC for Cosentyx is [redacted] per unit, with the most recent update to the WAC in January 2024. The initial WAC was [redacted] in January 2015. This is a 116.64% increase from January 2015 to January 2024, a 43.06% increase in the past five years, and a 7.00% increase from 2023. The average course of treatment is [redacted] units per patient per year, making the current WAC per course of treatment [redacted].[2]

[1] https://www.bls.gov/regions/mountain-plains/news-release/ConsumerPriceIndex_Denver.htm. Annual inflation numbers were for all items, not seasonally adjusted, with the current base (1982-40 = 100) and inflation change was calculated on an annual basis.

[2] For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

In October of 2023, the FDA approved Cosentyx to treat a new indication, hidradenitis suppurativa (HS).[3] The subcutaneous administration of Cosentyx to treat HS has the same WAC as below, but treating HS with Cosentyx also involves an intravenous administration which has a WAC of [redacted] per unit and which has not changed since it was introduced. Please see Table A-1 below for more information. This appendix shows the subcutaneous administration of 150 MG/ML of Cosentyx and the most common dose of Cosentyx is two units or 300 MG/ML.[4]

Table A-1

WAC per unit: Date, Price, and Percent Increase (Cosentyx[5])

Cosentyx WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	6.90%
[redacted]	[redacted]	4.00%
[redacted]	[redacted]	6.00%
[redacted]	[redacted]	2.70%
[redacted]	[redacted]	6.50%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	7.00%
[redacted]	[redacted]	7.00%
[redacted]	[redacted]	7.00%
[redacted]	[redacted]	2.00%
[redacted]	[redacted]	7.00%
[redacted]	[redacted]	7.00%

Table A-1 shows all historic WAC per unit amounts for Cosentyx and the percent difference of each change.

[3] Cosentyx FDA label: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

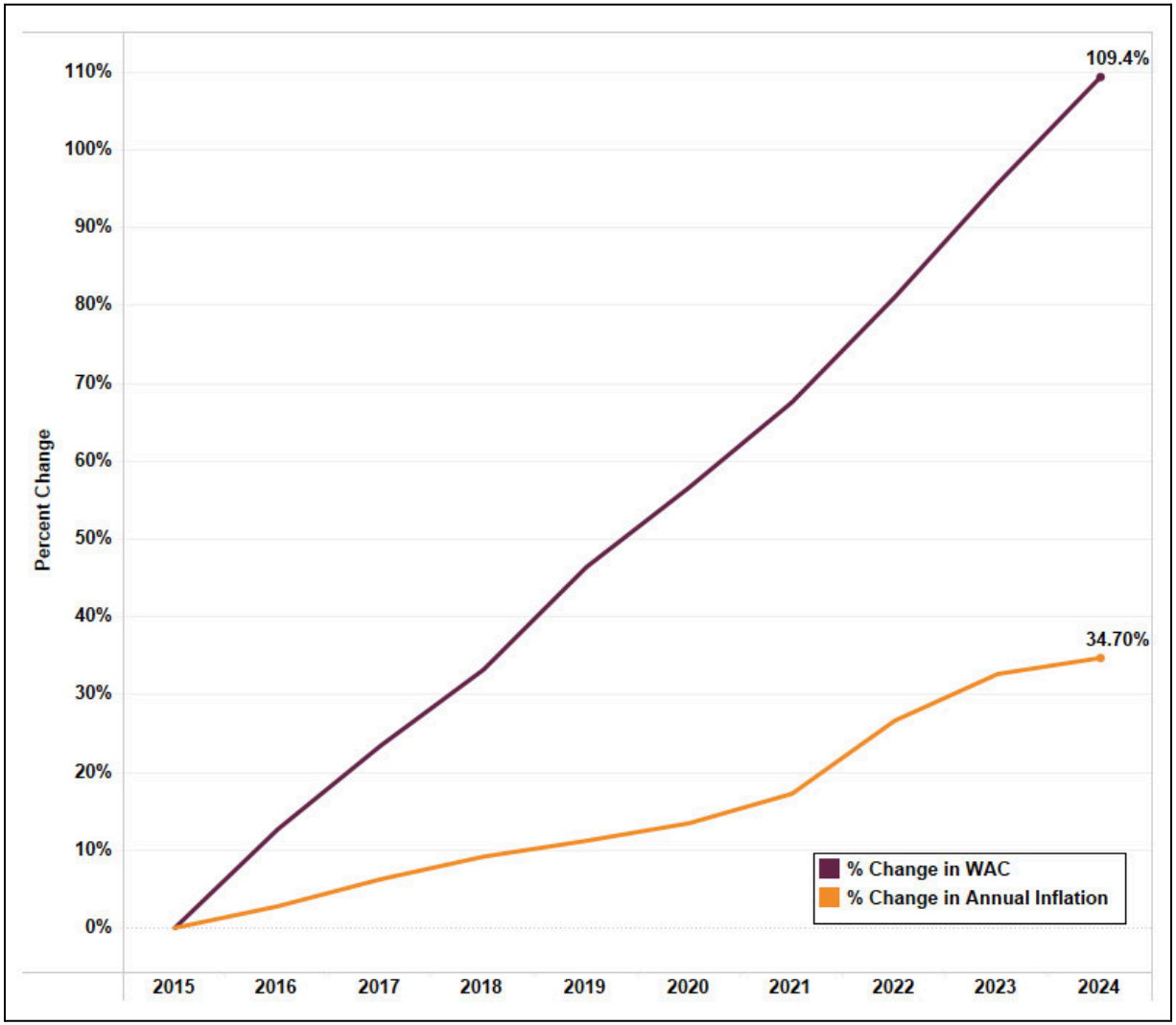
[4] The WAC is the same for a syringe or pen injector but may vary based on package size.

[5] WAC prices shown for the subcutaneous administration of 150 MG/ML of Cosentyx. The most common dosage of Cosentyx is 300 MG/ML, so most individuals take two doses at a time. See table A-3 for more information.

Figure A-1
Change in WAC per Unit Price (Cosentyx)

Figure A-1 shows the change in WAC per unit price since Cosentyx's initial WAC price in 2015.

Figure A-2
Percentage Change in WAC (Cosentyx)



For additional context, Figure A-2 shows the same change in WAC as a percent change (purple) and annual inflation (orange) over the same time frame.[6]

[6] Figure A-2 shows a comparison with inflation, which was not calculated for the complete year of 2023 at the time of this report, so the most recent WAC price is not included in this graphic and the percent change in WAC noted here is from 2018 through 2022.

Figure A-3

WAC per Course of Treatment for Cosentyx and Therapeutic Alternatives

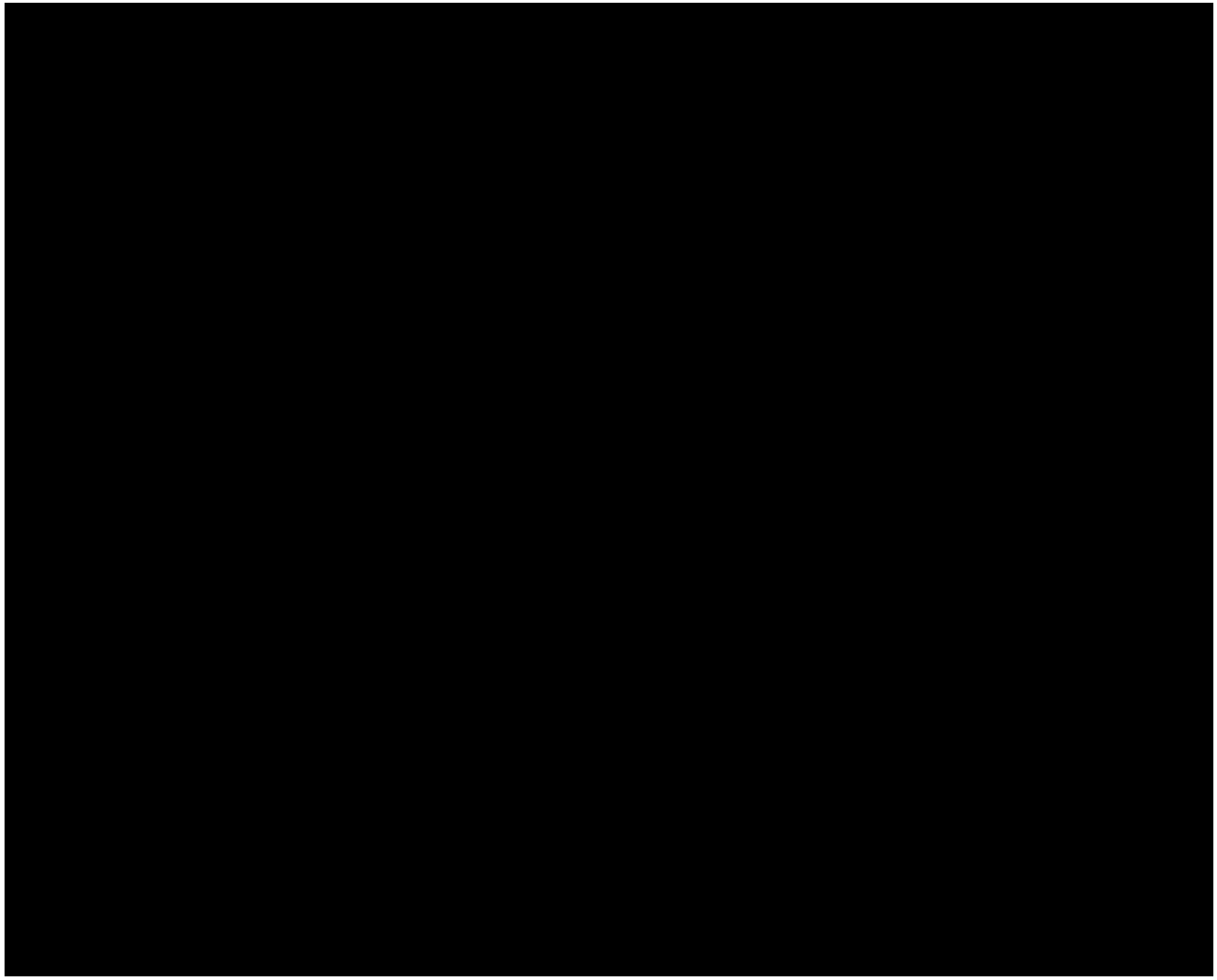


Figure A-3 shows the changes in WAC per course of treatment for Cosentyx and identified therapeutic alternatives.[7] This graphic highlights the changes in WAC for each drug, as listed in table A-2 below, as well as the WAC per course of treatment of each drug as determined by average utilization in Colorado. If a line does not continue to the end of the figure, it is because the WAC has not changed from the last year displayed.

[7] The course of treatment calculation used in selecting drugs, calculated from 2021 APCD claims experience was used across all time frames to highlight the changes in WAC relative to each drug. For course of treatment methodology please see June 6, 2023 PDAB Board staff memo: https://drive.google.com/file/d/16BFOEB-LMiulmYzhKhxeGjvbFoh88cTs/view?usp=sharing

Table A-2
WAC Changes from Initial and within the Last 5 Years for Therapeutic Alternatives

Ilumya WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	4.97%
[redacted]	[redacted]	5.00%
[redacted]	[redacted]	6.00%
[redacted]	[redacted]	6.00%

Siliq WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	-7.23%
[redacted]	[redacted]	6.00%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	9.90%
[redacted]	[redacted]	9.90%

Skyrizi[8] WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	7.40%
[redacted]	[redacted]	7.99%
[redacted]	[redacted]	6.50%

[8] Only the subcutaneous administration of the 150 mg/mL strength is listed for comparison to Cosentyx. For more details, please see Table A-3.

Stelara WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	4.90%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.40%
[redacted]	[redacted]	4.00%
[redacted]	[redacted]	5.00%

Taltz WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	38.66%
[redacted]	[redacted]	5.00%
[redacted]	[redacted]	4.99%
[redacted]	[redacted]	5.00%
[redacted]	[redacted]	5.00%

Tremfya WAC per Unit Effective Date	WAC per Unit Price	Percent Increase from Previous Price
[redacted]	[redacted]	
[redacted]	[redacted]	17.63%
[redacted]	[redacted]	4.80%
[redacted]	[redacted]	5.40%
[redacted]	[redacted]	5.00%
[redacted]	[redacted]	5.00%

Table A-2 shows the initial WAC and any changes in WAC in the last five years for identified therapeutic alternatives.[9]

Table A-3
FDA Recommended Dosage by Drug & Indication

Drug Name	Indication	FDA Recommended Dosage
Cosentyx[10]	Adult and pediatric plaque psoriasis (PsO)	**Adult subcutaneous dosage** • 300 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. Each 300 mg dosage is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg. A 150 mg dose may be appropriate for some patients. **Pediatric subcutaneous dosage (6 years and older)** • Weight-based dosage administered at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. For patients < 50 kg (at the time of dosing), the recommended dose is 75 mg. For patients ≥ 50 kg (at the time of dosing), the recommended dose is 150 mg.

	Adult and pediatric psoriatic arthritis (PsA)	Can be administered with or without methotrexate
		Adult subcutaneous dosage
		• For adult patients with PsA and with coexistent moderate to severe PsO, use the dosage and administration recommendations for adults with PsO.
		• For other adult patients with PsA, with a loading dosage is 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. Without a loading dosage is 150 mg every 4 weeks.
		• If a patient continues to have active PsA, consider increasing the dosage to 300 mg every 4 weeks, administered as one subcutaneous injection of 300 mg or two subcutaneous injections of 150 mg.
		Pediatric subcutaneous dosage (2 years and older)
		• Weight-based subcutaneous dosage at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter:
		  ○ For patients ≥ 15 kg and < 50 kg, the recommended dose is 75 mg.
		  ○ For patients ≥ 50 kg, the recommended dose is 150 mg.
		Adult intravenous dosage
		• With a loading dosage:6 mg/kg loading dose given at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter (maintenance dosage).
		• Without a loading dosage: 1.75 mg/kg every 4 weeks.
		• Administer as an intravenous infusion over a period of 30 minutes. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in adults with PsA

	Adult ankylosing spondylitis (AS)	**Subcutaneous dosage** • With a loading dosage is 150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. Without a loading dosage is 150 mg every 4 weeks.

[9] The first percent increase may cover up to 16 years, which is why some of the initial increases appear to be larger. Where there are multiple WACs per unit for a drug, only one strength and dosage form is included to display the increases in identified therapeutic alternatives.
[10] www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

		• If a patient continues to have active AS, consider increasing the dosage to 300 mg every 4 weeks by subcutaneous injection, administered as one subcutaneous injection of 300 mg or two subcutaneous injections of 150 mg. **Intravenous dosage** • With a loading dosage: 6 mg/kg loading dose given at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter (maintenance dosage). Without a loading dosage:1.75 mg/kg every 4 weeks. Administer as an intravenous infusion over a period of 30 minutes. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in patients with AS
	Adult non-radiographic axial spondyloarthritis (nr-axSpA)	**Subcutaneous dosage** • With a loading dosage:150 mg at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. Without a loading dosage:150 mg every 4 weeks. **Intravenous dosage** • With a loading dosage: 6 mg/kg loading dose given at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter (maintenance dosage). Without a loading dosage:1.75 mg/kg every 4 weeks. Administer as an intravenous infusion over a period of 30 minutes. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in patients with nr-axSpA
	Pediatric active enthesitis-related arthritis (ERA)	**Pediatric subcutaneous dosage (4 years and older)** • Weight-based dosage at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter: ○ For patients ≥ 15 kg and < 50 kg: 75 mg. ○ For patients ≥ 50 kg: 150 mg.
	Adult hidradenitis suppurativa (HS)	**Subcutaneous dosage** • 300 mg at Weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter. If a patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks.Each 300 mg dosage is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.
Therapeutic Alternative	**Indication[11]**	**FDA Recommended Dosage**
Bimzelx[12]	Adult plaque psoriasis (PsO)	320 mg (two 160 mg subcutaneous injections) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing ≥ 120 kg, consider a dose of 320 mg every 4 weeks after Week 16. (
Ilumya[13]	Adult plaque psoriasis (PsO)	100 mg administered by subcutaneous injection at Weeks 0, 4, and every 12 weeks thereafter.

[11] This table shows indications that each therapeutic alternative shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.
[12] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761151s000lbl.pdf
[13] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761067s018lbl.pdf

Siliq[14]	Adult plaque psoriasis (PsO)	210 mg by subcutaneous injection at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks.
Skyrizi[15]	Adult plaque psoriasis (PsO)	150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.
	Adult psoriatic arthritis (PsA)	150 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter. Can be administered alone or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs).
Stelara[16]	Adult and pediatric plaque psoriasis (PsO)	**Adult subcutaneous dosage** • ≤ 100 kg: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks • >100 kg: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks **Pediatric subcutaneous dosage (6 years and older)** Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. • <60 kg: 0.75 mg/kg • 60 kg - 100 kg: 45 mg • >100 kg: 90 mg
	Adult and pediatric psoriatic arthritis (PsA)	**Adult subcutaneous dosage** • 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. • For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg: 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. **Pediatric subcutaneous dosage (6 years and older)** Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter. • <60 kg: 0.75 mg/kg • 60 kg or more: 45 mg • >100 kg with coexistent moderate-to-severe plaque psoriasis: 90 mg
Taltz[17]	Adult and pediatric plaque psoriasis (PsO)	**Adult subcutaneous dosage** 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks **Pediatric subcutaneous dosage (6 years and older)** • >50 kg: 160 mg (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks. • 25-50 kg: 80 mg at Week 0, followed by 40 mg every 4 weeks. • <25 kg: 40 mg at Week 0, followed by 20 mg every 4 weeks.

[14] https://www.accessdata.fda.gov/spl/data/044e3e17-7930-63ae-e063-6294a90acb9b/044e3e17-7930-63ae-e063-6294a90acb9b.xml
[15] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761105s027,761262s008lbl.pdf
[16] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761044s013lbl.pdf
[17] https://www.accessdata.fda.gov/spl/data/02b8e3f2-ea8d-427e-97ae-392c1245e1b0/02b8e3f2-ea8d-427e-97ae-392c1245e1b0.xml

	Adult psoriatic arthritis (PsA)	160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks. For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for adult PsO.
	Adult ankylosing spondylitis (AS)	Recommended dosage is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
	Adult non-radiographic axial spondyloarthritis (nr-axSpA)	Recommended dosage is 80 mg by subcutaneous injection every 4 weeks.
Tremfya[18]	Adult plaque psoriasis (PsO)	100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter.
	Adult psoriatic arthritis (PsA)	100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter. Can be used alone or in combination with a conventional DMARD (e.g. methotrexate).

Table A-3 shows the FDA label's suggested dosing for each indication of Cosentyx and identified therapeutic alternatives.

[18] https://www.accessdata.fda.gov/spl/data/09bab28f-d731-f2e7-e063-6294a90a1b79/09bab28f-d731-f2e7-e063-6294a90a1b79.xml

Appendix B

Cosentyx: Therapeutic Alternatives

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the cost and availability of therapeutic alternatives to the prescription drug in the state. (C.R.S. § 10-16-1406(4)(b)).

Rule: The Board will consider the cost and availability of therapeutic alternatives to the prescription drug in the state. The Board may review any relevant data regarding costs and expenditures related to the prescription drug and its therapeutic alternatives, as well as any relevant data regarding availability and utilization related to the prescription drug and its therapeutic alternatives. (3 CCR 702-9, Part 3.1.E.2.b).

Therapeutic alternative is defined as a drug product that contains a different therapeutic agent than the drug in question, but is the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines. (3 CCR 702-9, Part 1.1.C)

Policy: Information containing a list of therapeutic alternatives for the Board's consideration through review and consultation of sources such as the Orange Book, the Purple Book, World Health Organization's anatomical therapeutic classification code system, and peer-reviewed research. Information prepared for the Board's consideration includes:

- The cost of the therapeutic alternative in the state by examining APCD expenditure data or other data sources relevant to cost of the therapeutic alternatives in the state;
- The availability of the therapeutic alternative in the state by examining APCD utilization data or other data sources relevant to the therapeutic alternatives in the state; and
- Rebate data for the therapeutic alternative(s) by examining external databases. (PDAB Policy 04, p. 6).

Underlying Methodology: Board staff and members of the Program on Regulation, Therapeutics, and Law (PORTAL) have compiled data for Cosentyx and its therapeutic alternatives for the Board's consideration in the following manner:

1. Identified in-class therapeutic alternatives for Cosentyx.
2. Presented utilization data from 2018-2022, including both units utilized and the number of patients who utilized the prescription drug.
3. Presented expenditure data from 2018-2022, including total paid amount, total plan paid amount, total patient paid amount, average paid per person per year, and average patient out-of-pocket cost per person per year.
4. Examined rebate estimates, when available, for selected prescription drugs and therapeutic alternatives.

Data Source(s): Members of PORTAL assisted Board staff in compiling information on therapeutic alternatives of Cosentyx. Data sources used to identify therapeutic alternatives include:

- FDA website, which contains information on current FDA labeling for each drug and FDA-approved indication.
- Websites of medical professional organizations for specific disease areas to identify medical association guidelines.
- UpToDate, an online, evidence-based clinical decision support database, to identify therapeutic alternatives that may have been approved since the most recent medical association guidelines.

Considerations and Data Limitations:

- Medical professional association guidelines used in this affordability review component are often unique to a particular indication and authored by different professional associations. As such, these guidelines are not consistently organized or structured.
- Medical professional guidelines may be published every several years. As such, there may be instances where the selected drug or therapeutic alternatives are not in the most recent medical professional association guidelines. If this is the case, it will be noted.

Cosentyx: Therapeutic Alternatives Evidence

Therapeutic Alternatives Identification

Members of PORTAL identified therapeutic alternatives in the following manner:

1. Identified the Cosentyx's therapeutic class as defined under the WHO Anatomical Therapeutic Chemical[1] (WHO-ATC) classification system. Only drugs listed in the same therapeutic class as Cosentyx under this system were evaluated as therapeutic alternatives.
2. Reviewed the current FDA labeling for Cosentyx and identified each FDA-approved indication. Pediatric and adult indications were reviewed separately if separate medical professional guidelines were available for the respective populations.
3. Identified U.S. medical professional association guideline(s), which rely upon peer-reviewed research, relevant to each FDA-approved indication done via internet search and reviewing the websites of medical professional organizations. If both U.S. and international guidelines were available, use the U.S. guidelines exclusively. If guidelines were available from multiple U.S. organizations, both were included.
4. Located Cosentyx in the guidelines to determine how the drug is recommended for use. For example, was the drug recommended as first-line treatment or subsequent line after failure of another treatment? Was it recommended for all patients or specific sub-populations? This was compared to the drug's FDA label, documenting any discrepancies and off-label uses.
5. Summarized the guideline recommendations and how the selected drug fits into those recommendations. This included information about how the treatment of different subpopulations may deviate from the standard pathway.
6. Within the guidelines, identified other drugs in the same WHO-ATC drug class that were recommended to be used similarly to the selected drug. For each in-class therapeutic alternative, identified the drug's non-proprietary name and brand name.
7. To identify in-class alternatives approved after guideline publication, reviewed treatment options for each indication via UpToDate[2], an online evidence-based clinical decision support database. If recently approved in-class drugs were identified that were not included in the guidelines, these drugs' labeling were reviewed and included as alternatives if the drug had an FDA-approved indication that matched that of the selected drug.
8. Used the FDA approval history database via Drugs.com to identify the estimated indication approval date for each therapeutic alternative. This date was verified using the Drugs@FDA database[3]. If drugs were recommended in the guidelines but were not FDA-approved for the indication, these will be marked as off-label alternatives.

[1] https://www.whocc.no/atc_ddd_index/
[2] https://www.wolterskluwer.com/en/solutions/uptodate
[3] https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases

Board Consideration of Therapeutic Alternatives to Cosentyx

During the Board's September 15, 2023 meeting, the Board directed Board staff to narrow data analyses of APCD, WAC, and rebate data for purposes of this component to those therapeutic alternatives that are in the same class as Cosentyx.[4]

FDA Indication and Therapeutic Alternatives

Cosentyx's therapeutic class as defined under the WHO-ATC classification system is interleukin inhibitors[5]. The following guidelines were used to identify in-class therapeutic alternatives for all FDA-approved indications in Table B-1.

Table B-1

Cosentyx Indications and Relevant Guidelines

FDA[6] Approved Indications (as of October 2023)	Relevant Guidelines	Guideline Publication Date
Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy.	Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics[7]	2/13/2019
Active psoriatic arthritis (PsA) in patients 2 years of age and older.	2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis[8]	11/30/2018
Adults with active ankylosing spondylitis (AS).	2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis[9]	8/22/2019
Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.	2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis[10]	8/22/2019
Active enthesitis-related arthritis (ERA) in pediatric patients 4 years of age and older.	2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis[11]	4/25/2019
Adults with moderate to severe hidradenitis suppurativa (HS)	North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management[12]	6/20/2019

[4] The Board also gave staff approval to only look at one-dose regimens if the selected drug was also one-dose. That is not the case for Cosentyx.
[5] https://www.whocc.no/atc_ddd_index/?code=L04AC&showdescription=no
[6] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf
[7] https://pubmed.ncbi.nlm.nih.gov/30772098/
[8] https://doi.org/10.1002/art.40726
[9] https://doi.org/10.1002/art.41042
[10] https://doi.org/10.1002/art.41042
[11] https://doi.org/10.1002/acr.23870
[12] https://www.sciencedirect.com/science/article/pii/S0190962219303688?via%3Dihub

Table B-1 shows the FDA approved indication for Cosentyx and relevant guidelines and guideline publication date.

In-Class Therapeutic Alternatives

The relevant guidelines outlined above identify the following in-class therapeutic alternatives for Cosentyx:

- Bimzelx
- Ilumya
- Siliq
- Skyrizi
- Stelara
- Taltz
- Tremfya

Bimzelx

- **Non-Proprietary Name:** bimkizumab-bkzx
- **Brand Name:** Bimzelx
- **Mechanism of Action:** IL-17A/17F inhibitor

Table B-2
Bimzelx: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Plaque psoriasis (PsO)	New: Bimzelx was approved for adult PsO after guideline publication.	10/17/23 in adults only
Psoriatic arthritis (PsA)	Bimzelx is not FDA-approved for this indication.	
Ankylosing spondylitis (AS)	Bimzelx is not FDA-approved for this indication.	
Non-radiographic axial spondyloarthritis (nr-axSpA)	Bimzelx is not FDA-approved for this indication.	
Pediatric active enthesitis-related arthritis (ERA)	Bimzelx is not FDA-approved for this indication.	
Hidradenitis suppurativa (HS)	Bimzelx is not FDA-approved for this indication.	

Table B-2 shows the indications Bimzelx shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.

Ilumya

- **Non-Proprietary Name:** tildrakizumab-asmn
- **Brand Name:** Ilumya
- **Mechanism of Action:** IL-23 inhibitor

Table B-3
Ilumya: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Plaque psoriasis (PsO)	Yes	3/20/2018 in adults only
Psoriatic arthritis (PsA)	Ilumya is not FDA-approved for this indication.	
Ankylosing spondylitis (AS)	Ilumya is not FDA-approved for this indication.	
Non-radiographic axial spondyloarthritis (nr-axSpA)	Ilumya is not FDA-approved for this indication.	
Pediatric active enthesitis-related arthritis (ERA)	Ilumya is not FDA-approved for this indication.	
Hidradenitis suppurativa (HS)	Ilumya is not FDA-approved for this indication.	

Table B-3 shows the indications Ilumya shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.

Siliq

- **Non-Proprietary Name:** brodalumab
- **Brand Name:** Siliq
- **Mechanism of Action:** IL-17 inhibitor

Table B-4
Siliq: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Plaque psoriasis (PsO)	Yes	2/15/2017 in adults only
Psoriatic arthritis (PsA)	In guidelines, off-label (not FDA approved)	N/A
Ankylosing spondylitis (AS)	Siliq is not FDA-approved for this indication.	
Non-radiographic axial spondyloarthritis (nr-axSpA)	Siliq is not FDA-approved for this indication.	
Pediatric active enthesitis-related arthritis (ERA)	Siliq is not FDA-approved for this indication.	
Hidradenitis suppurativa (HS)	Siliq is not FDA-approved for this indication.	

Table B-4 shows the indications Siliq shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.

Skyrizi

- **Non-Proprietary Name:** risankizumab-rzaa
- **Brand Name:** Skyrizi
- **Mechanism of Action:** IL-23 inhibitor

Table B-5
Skyrizi: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Plaque psoriasis (PsO)	Yes	4/23/2019 in adults only
Psoriatic arthritis (PsA)	In guidelines, off-label at time of publication (now FDA approved)	1/21/2022 in adults only
Ankylosing spondylitis (AS)	Skyrizi is not FDA-approved for this indication.	
Non-radiographic axial spondyloarthritis (nr-axSpA)	Skyrizi is not FDA-approved for this indication.	
Pediatric active enthesitis-related arthritis (ERA)	Skyrizi is not FDA-approved for this indication.	
Hidradenitis suppurativa (HS)	Skyrizi is not FDA-approved for this indication.	

Table B-5 shows the indications Skyrizi shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.

Stelara

- **Non-Proprietary Name:** ustekinumab
- **Brand Name:** Stelara
- **Mechanism of Action:** IL-12/IL-23 inhibitor

Table B-6
Stelara: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Adult and pediatric plaque psoriasis (PsO)	Yes	9/25/2009
Adult and pediatric psoriatic arthritis (PsA)	Yes	9/20/2013
Ankylosing spondylitis (AS)	Stelara is not FDA-approved for this indication.	
Non-radiographic axial spondyloarthritis (nr-axSpA)	Stelara is not FDA-approved for this indication.	
Pediatric active enthesitis-related arthritis (ERA)	Stelara is not FDA-approved for this indication.	
Hidradenitis suppurativa (HS)	Stelara is not FDA-approved for this indication.	

Table B-6 shows the indications Stelara shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.

Taltz

- **Non-Proprietary Name:** ixekizumab
- **Brand Name:** Taltz
- **Mechanism of Action:** IL-17A inhibitor

Table B-7
Taltz: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Plaque psoriasis (PsO)	Yes	3/22/2016 in adults 3/26/2020 in pediatric
Psoriatic arthritis (PsA)	Yes	12/1/2017 in adults only
Ankylosing spondylitis (AS)	Yes	8/23/2019
Non-radiographic axial spondyloarthritis (nr-axSpA)	Yes	5/29/2020
Pediatric active enthesitis-related arthritis (ERA)	Taltz is not FDA-approved for this indication.	
Hidradenitis suppurativa (HS)	Taltz is not FDA-approved for this indication.	

Table B-7 shows the indications Taltz shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.

Tremfya

- **Non-Proprietary Name:** guselkumab
- **Brand Name:** Tremfya
- **Mechanism of Action:** IL-23 inhibitor

Table B-8
Tremfya: In-Class Therapeutic Alternatives by Indication

Indication	In Guidelines	FDA Approval Date
Plaque psoriasis (PsO)	Yes	7/13/2017 in adults only
Psoriatic arthritis (PsA)	New: Tremfya was approved for adult PsA after guideline publication.	7/13/2020 in adults only
Ankylosing spondylitis (AS)	Tremfya is not FDA-approved for this indication.	
Non-radiographic axial spondyloarthritis (nr-axSpA)	Tremfya is not FDA-approved for this indication.	
Pediatric active enthesitis-related arthritis (ERA)	Tremfya is not FDA-approved for this indication.	
Hidradenitis suppurativa (HS)	Tremfya is not FDA-approved for this indication.	

Table B-8 shows the indications Tremfya shares with Cosentyx. Therapeutic alternatives may be FDA-approved to treat other indications, but are not included in this table.

Appendix C

Cosentyx: Price Effect on Consumer Access

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the effect of the price on Colorado consumers' access to the prescription drug. (C.R.S. § 10-16-1406(4)(c)).

Rule: The Board will consider the effect of price on Colorado consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time. (3 CCR 702-9, Part 3.1.E.2.c).

Policy: Information regarding changes in pricing compared to changes in expenditure and utilization over the same time period to analyze potential correlation. Information will also be presented from APCD data and subject matter experts to better understand potential confounding variables, such as:

- When therapeutic alternative(s) were available;
- Changes to patents; and
- Changes in rebate amounts for the prescription drug or therapeutic alternative. (PDAB Policy 04, pp. 6-7).

Underlying Methodology: Board staff have compiled data on price effect on consumer access for the Board's consideration in the following manner:

1. From APCD pharmacy claims, Board staff pulled all claims for Cosentyx from October 2018 - December 2022.
2. Board staff combined the claims data with WAC data from AnalySource by joining on the month and year of the claim with the effective WAC of the same month and year.
3. Board staff combined the claims and WAC data with the gross-to-net sales estimates from SSR Health by joining the month and year of the claim with the month and year of the quarter estimates in SSR Health.

Data Source(s): Board staff compiled information on price effect on access for the selected prescription drug from the following sources:

- APCD, which provides detail on utilization and expenditure,
- AnalySource for current and historical WAC,
- FDA and Centers for Medicare and Medicaid Services (CMS) for other pricing data,
- FDA website for changes to patents, and
- SSR Health for gross-to-net sales estimates.

Considerations and Data Limitations: Claims-based utilization data shows what health care services were accessed, but this data does not show what health care services were potentially under-accessed or not accessed at all. Qualitative data (such as surveys or anecdotes) may illuminate which health care services were under-accessed or not accessed at all, but there is no validated data source that provides this information.

Cosentyx: Price Effect on Access Evidence

This appendix provides more detailed information regarding: utilization, price, out-of-pocket costs, and gross-to-net sales estimates, and patent information.

Table C-1

Changes in Cosentyx Utilization, Expenditure, and Gross-to-Net Sales from 2018-2022

	2018	2022	Percent Change
Total OOP Costs	$1,917	$3,297	71.99%
Total Paid Amount	$17,496,392	$52,957,875	202.68%
Patient Count	478	1,128	139.98%
Gross-to-Net Sales	[redacted]	[redacted]	[redacted]
WAC	[redacted]	[redacted]	[redacted]

Table C-1 shows the total out-of-pocket costs, the total paid amount, the total number of patients utilizing Cosentyx, and the gross-to-net sales estimate in 2018 and 2022 years, with the percent change over that time period. There was a 139.98% increase in the number of patients utilizing Cosentyx, a 202.68% increase in the total paid amount, and a 71.99% increase in total out-of-pocket expenses. During this timeframe there was a [redacted] 80% of Colorado respondents indicated that the cost of Cosentyx impacted their adherence. Please see appendices A, E, H, and K for more detail

Table C-2

Annual Utilization and Expenditures (All Lines of Business)

	2018	2019	2020	2021	2022
Patient Count	478	727	956	1,149	1,128
Total Paid	$17,496,392	$29,831,351	$43,762,979	$51,499,809	$52,957,875
Average Paid Per Person	$36,603	$41,033	$45,777	$44,821	$46,948
Total Patient Paid	$505,537	$903,303	$1,442,560	$2,721,858	$2,197,945
Average OOP Cost	$1,917	$2,113	$3,024	$4,048	$3,297
WAC per Unit	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table C-2 shows the year-over-year increases in the number of patients using Cosentyx, the total amount paid for Cosentyx, the average paid per person, the total amount that patients paid, and the average amount that each patient paid.

Table C-3

APCD Utilization and Cost, WAC, and Gross-to-Net Sales Estimates

Rx Fill Date	Patient Count	WAC per Unit	Gross-to-Net -Sales Est.	Total Paid	Average Paid	OOP Cost	Average Deductible	Average Coinsurance	Average Copay	Average Days Supply
January 2018	135	[redacted]	[redacted]	$1,068,035	$7,911	$513.44	$349.67	$68.35	$95.43	32
February 2018	163			$1,384,156	$8,491	$184.21	$70.16	$77.22	$36.83	39
March 2018	175			$1,367,925	$7,816	$201.23	$101.70	$56.92	$42.61	32
April 2018	172		[redacted]	$1,207,129	$7,018	$172.77	$65.66	$51.05	$56.07	31
May 2018	193			$1,556,300	$8,063	$170.28	$62.36	$56.41	$51.52	30
June 2018	202			$1,553,030	$7,688	$112.35	$31.82	$29.23	$51.30	33
July 2018	185		[redacted]	$1,310,842	$7,085	$73.52	$1.38	$22.22	$49.92	30
August 2018	205			$1,483,931	$7,238	$87.53	$21.26	$24.23	$42.05	32
September 2018	204			$1,560,942	$7,651	$85.26	$5.29	$41.98	$37.99	34
October 2018	229		[redacted]	$1,801,927	$7,868	$118.60	$45.31	$33.66	$39.63	30
November 2018	227			$1,554,208	$6,846	$96.34	$18.65	$41.58	$36.11	32
December 2018	228			$1,647,960	$7,227	$67.81	$7.91	$25.27	$34.63	34
January 2019	247	[redacted]	[redacted]	$2,099,901	$8,501	$405.00	$268.12	$69.14	$67.74	30
February 2019	258			$2,169,608	$8,409	$189.96	$87.17	$52.33	$50.45	31
March 2019	279			$2,249,032	$8,061	$226.80	$116.58	$60.40	$49.81	31
April 2019	275		[redacted]	$2,019,256	$7,342	$140.59	$27.94	$58.95	$53.70	30
May 2019	311			$2,872,602	$9,236	$102.73	$28.71	$38.47	$35.55	32
June 2019	301			$2,263,072	$7,518	$120.92	$27.47	$54.63	$38.83	32
July 2019	328		[redacted]	$2,659,468	$8,108	$109.46	$20.94	$40.76	$47.77	32

Rx Fill Date	Patient Count	WAC per Unit	Gross-to-Net -Sales Est.	Total Paid	Average Paid	OOP Cost	Average Deductible	Average Coinsurance	Average Copay	Average Days Supply
August 2019	312			$2,464,631	$7,899	$139.52	$40.72	$56.79	$42.01	31
September 2019	325			$2,387,781.47	$7,347	$111.47	$35.38	$41.87	$34.21	30
October 2019	350		[redacted]	$2,998,520.89	$8,567	$128.65	$28.27	$58.05	$42.32	31
November 2019	347			$2,836,539.72	$8,174	$100.22	$32.82	$36.69	$30.76	29
December 2019	366			$2,810,936.01	$7,680	$142.43	$25.21	$68.73	$48.49	30
January 2020	360	[redacted]	[redacted]	$3,188,674.04	$8,857	$426.20	$312.67	$57.89	$55.64	29
February 2020	381			$3,066,725.04	$8,049	$300.90	$130.71	$104.10	$66.08	31
March 2020	407			$3,785,160.70	$9,300	$207.81	$68.92	$69.07	$69.93	31
April 2020	429		[redacted]	$3,338,286.01	$7,781	$133.83	$46.26	$40.01	$47.56	30
May 2020	427			$3,614,466.12	$8,464	$123.46	$28.98	$49.19	$45.34	33
June 2020	464			$3,557,645.53	$7,667	$99.83	$13.65	$33.46	$52.73	30
July 2020	469		[redacted]	$3,522,360.34	$7,510	$136.94	$51.34	$41.41	$44.26	30
August 2020	475			$3,529,894.44	$7,431	$112.17	$20.17	$49.53	$42.46	30
September 2020	515			$3,761.935.63	$7,304	$87.80	$6.95	$43.97	$33.81	32
October 2020	513		[redacted]	$3,916,930.63	$7,635	$58.87	$8.26	$28.59	$22.02	33
November 2020	520			$4,224,706.73	$8,124	$131.75	$53.62	$43.92	$34.33	31
December 2020	551			$4,256,193.39	$7,724	$135.38	$47.60	$53.04	$34.86	31
January 2021	577	[redacted]	[redacted]	$6,189,879.82	$10,727	$483.37	$411.87	$36.74	$34.76	34
February 2021	566			$4,082,817.80	$7,213	$214.92	$131.08	$42.86	$40.98	31
March 2021	603			$4,670,080.94	$7,744	$194.11	$95.36	$49.68	$49.22	32
April 2021	574		[redacted]	$4,004,777.34	$6,976	$157.95	$62.19	$45.99	$49.82	30

Rx Fill Date	Patient Count	WAC per Unit	Gross-to-Net -Sales Est.	Total Paid	Average Paid	OOP Cost	Average Deductible	Average Coinsurance	Average Copay	Average Days Supply
May 2021	559			$3,883,287.09	$6,946	$163.61	$62.04	$42.89	$58.68	31
June 2021	580			$4,208,578.50	$7,256	$123.06	$27.11	$42.70	$53.30	34
July 2021	589		[redacted]	$4,322,378.92	$7,338	$251.99	$110.28	$80.59	$61.13	35
August 2021	567			$3,964,550.73	$6,992	$133.76	$26.03	$40.14	$67.58	31
September 2021	564			$3,994,240.05	$7,081	$117.31	$20.64	$33.94	$62.73	30
October 2021	580		[redacted]	$4,135,049.23	$7,129	$119.83	$28.67	$46.04	$45.12	33
November 2021	573			$4,065,930.21	$7,095	$96.09	$23.47	$29.91	$42.71	32
December 2021	558			$3,978,237.97	$7,129	$109.06	$28.67	$34.17	$46.22	30
January 2022	524		[redacted]	$3,967,992.67	$7,572	$471.21	$277.69	$81.09	$112.42	30
February 2022	558			$3,896,200.30	$6,982	$217.61	$57.76	$83.43	$76.60	31
March 2022	610			$4,590,623.50	$7,525	$178.05	$42.20	$70.39	$65.45	36
April 2022	586		[redacted]	$5,135,713.83	$8,764	$175.83	$58.07	$51.04	$66.72	31
May 2022	620			$4,656,051.58	$7,509	$199.71	$38.58	$81.09	$80.05	32
June 2022	602			$4,571,597.05	$7,594	$184.18	$26.47	$94.79	$62.92	30
July 2022	553	[redacted]	[redacted]	$3,739,294.78	$6,761	$209.23	$22.39	$110.20	$76.64	31
August 2022	586			$5,237,465.71	$8,937	$148.43	$28.04	$54.06	$66.33	31
September 2022	607			$3,980,857.48	$6,558	$115.08	$13.95	$41.31	$59.82	32
October 2022	580		[redacted]	$5,349,521.55	$9,223	$143.98	$13.39	$87.75	$42.84	29
November 2022	591			$3,961,239.12	$6,702	$107.10	$9.97	$35.83	$61.30	29
December 2022	578			$3,871,317.71	$6,697	$162.20	$69.24	$42.95	$50.01	30

Table C-3 above shows the monthly amounts of APCD, WAC, and gross-to-net sales estimates for Cosentyx. Columns in this table are defined below and all columns are from APCD data unless otherwise noted:

- **Month, Year of Rx Fill Date:** The month and year the prescription was filled. All data in this table is aggregated to the month and year.
- **Patient count:** The total number of patients who filled a prescription that month.
- **WAC per unit:**[1] The per unit WAC amount that was effective that month.
- **Gross-to-net sales estimate:**[2] The gross-to-net sales estimate of that quarter. Estimates are on a rolling four quarter average, so each estimate covers the previous year. Estimates appear in the first month of each quarter.
- **Total Paid:** The total amount paid for Cosentyx that month, inclusive of payer(s) and patient paid amounts.
- **Average Paid:** The average paid per person for that month.
- **Out-of-pocket Cost:** The average out-of-pocket cost (total of copayment, coinsurance, and deductible) per person that month.
- **Average Deductible Amount:** The average amount that individuals with commercial insurance and Medicare Advantage coverage paid towards their deductible that month. Note the generally higher amounts at the beginning of each year indicating patients contributing to their deductible with lower amounts later in the benefit plan year when the deductible has been met.
- **Average Coinsurance Amount:** The average amount that individuals with commercial insurance and Medicare Advantage coverage paid towards coinsurance that month. Potential to note that this is increasing.
- **Average Copayment Amount:** The average amount that individuals with commercial insurance and Medicare Advantage coverage paid in copayments that month.
- **Average Days Supply:** The average days supply that was filled with prescriptions that month.
- **Per Unit Cost:** The average per unit cost of the total amount paid per unit distributed. As Cosentyx was approved in October 2019, earlier estimates show a ramp of utilization as patients began taking the drug and early estimates may not show an accurate representation of all eligible patients taking the drug.

[1] First Databank, AnalySource

[2] SSR Health Estimates

Figure C-1
Monthly Total Paid and Average Total Paid

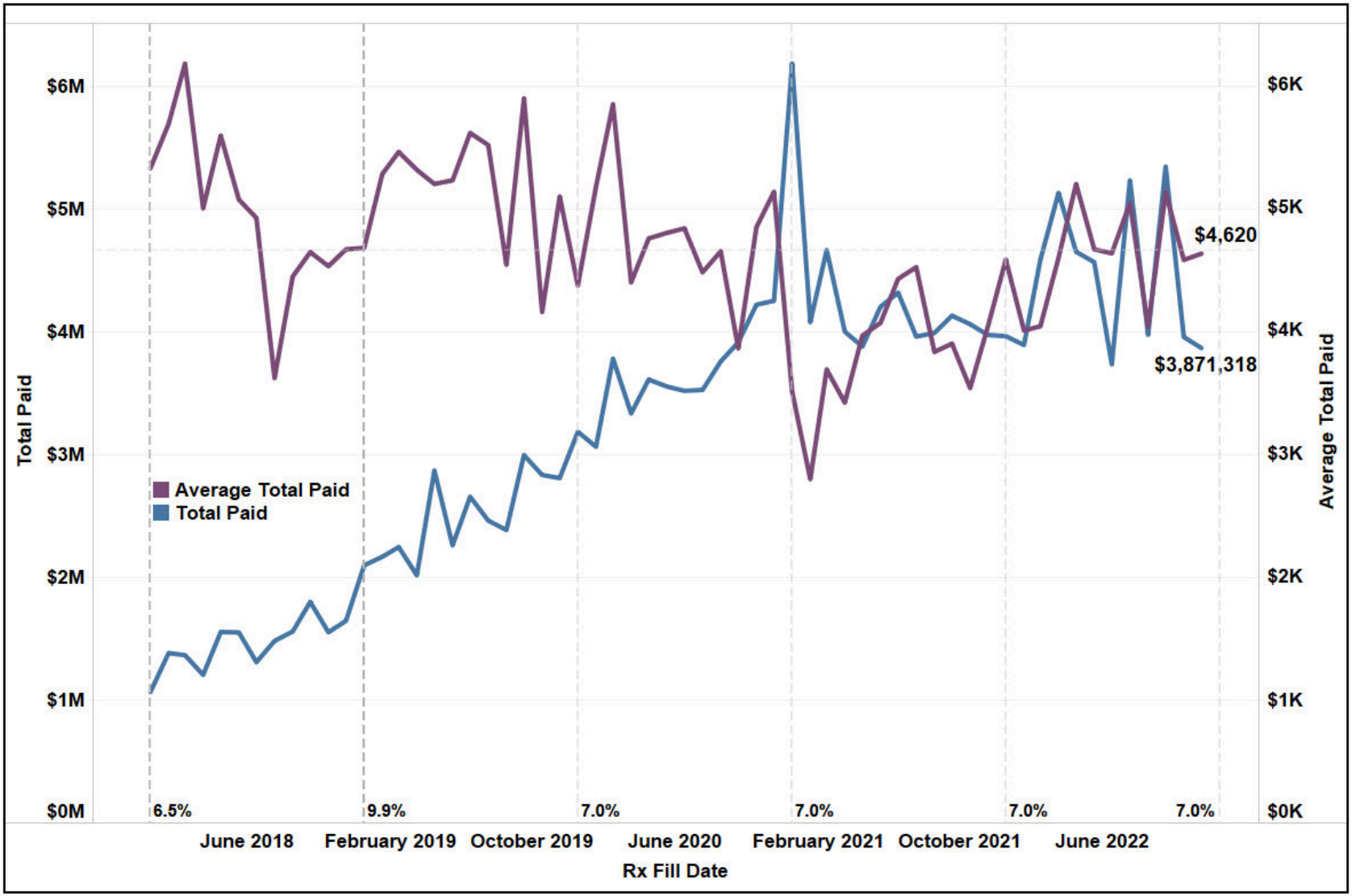


Figure C-1 shows the monthly total paid with the blue line (left axis) and the monthly average paid per person with the purple line (right axis) with vertical lines representing changes in WAC with the magnitude of the change written to the right of the line with an arrow up or down indicating an increase or decrease in the WAC. There is no visible correlation between the WAC change and the corresponding change in the APCD paid amounts. During this time frame, the number of patients using Cosentyx increased from 478 in 2018 to 1,128 in 2022.

Patents and Exclusivity

There are several ways for prescription drugs to gain exclusivity, which is a period of time when a brand-name drug is protected from generic competition. Cosentyx is a biologic drug that does not have any patent data in the FDA purple book[3] or in the I-MAK database[4], so all patent information is from Novartis' latest SEC 20-F filing from January 31, 2024: "Cosentyx. US: Five patents on composition of matter (2025 (4), 2026), PTE (2029); patent on psoriatic arthritis use (2031); patent on psoriasis use (2032); two patents on ankylosing spondylitis use (2032, 2033)".[5] There is no biosimilar competition for Cosentyx and the latest patent described in the 20-F filing is set to expire in 2033. Evaluating patents and other sources of exclusivity can be helpful in understanding potential access concerns, because there is evidence that such market conditions are associated with increased drug prices, limited availability, and increased costs to consumers and payers.[6]

[3] FDA purple Book: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or

[4] I-MAK's 'The Drug Patent Book' https://drugpatentbook.i-mak.org/.

[5] https://www.sec.gov/Archives/edgar/data/1114448/000137036824000004/nvs-20231231.htm

[6] https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00826-4

Appendix D

Cosentyx: Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Service Costs

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. (C.R.S. § 10-16-1406(4)(d)).

Rule: To the extent such information can be quantified, the Board may consider the relative financial effects of the prescription drug on broader health, medical, and/or social services costs, compared with therapeutic alternatives and/or no treatment. This may include considering results from external analyses and modeling studies.

- The Board may identify if the literature uses a quality-adjusted life-year analysis or a similar measure that discounts the value of a life because of an individual's disability or age. The Board may use information that uses a quality-adjusted life year analysis to evaluate relative financial effects, but will not use quality adjusted life year analysis to determine an upper payment limit or other appropriate costs of a prescription drug. If quality-adjusted life year analysis is used during affordability review, the Board will acknowledge any health equity impacts to priority populations. (3 CCR 702-9, Part 3.1.E.2.d).

Policy: Information providing an overview of the research regarding the relative financial effects of the prescription drug on health, medical, or social services costs. This will be done by reviewing research that is:

- Publicly available;
- To the extent the Board has funding, data accessible from the Drug Effectiveness Review Project; or
- Is voluntarily provided by manufacturers. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data for Cosentyx for the Board's consideration in the following manner:

1. Staff reviewed the current FDA labeling for each selected drug and identified each FDA-approved indication.
2. Identified relevant medical professional guidelines and manufacturer's purported benefits by indication.
3. Found evidence supporting the purported benefits by indication and compared the clinical effectiveness of therapeutic alternatives to each drug under review.[1]
4. Assessed the financial effects of a drug compared to its therapeutic alternatives.[2] This was completed for this appendix by examining studies with cost effectiveness analyses. Staff will note when studies use a quality-adjusted-life-year (QALY) or similar measure. The Affordability Review Summary Report may incorporate additional information of a prescription drug's financial effects that is not reported in this appendix, but was gathered from patients and caregivers, individuals with scientific and medical training, or provided in voluntarily submitted information.

[1] Staff will note when studies evaluate the clinical effectiveness of a therapeutic alternative that is not being considered by the Board in Appendix B. Further, staff will note when studies compare the clinical effectiveness of each drug under review to a placebo (i.e., when there is not a comparison to a therapeutic alternative).
[2] Id.

Considerations and Data Limitations: Staff provided citations for any literature utilized to compile evidence for this component, but some studies may need a subscription for the public to access. Additionally, studies frequently outline limitations. Staff will note these limitations and also note any differences in the specific strengths and dosage forms utilized in studies.

Cosentyx: Relative Financial Effects Evidence

Background

One component of affordability reviews is an assessment of the relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug. This sort of assessment is commonly referred to as a health technology assessment (HTA), which may be used by organizations or governments to systematically evaluate the effects and impacts of health care technology, or, relevant to this work, prescription drugs.[3] HTAs may address the direct, intended consequences of a prescription drug as well as a drug's indirect, unintended consequences. While some other countries (e.g., the United Kingdom, Canada) use governmental HTAs to guide prescription drug coverage and reimbursement policies, the United States does not have a government-run HTA body.

While the FDA is the primary federal regulator of prescription drugs in the United States, the agency does not take a big role in regulating HTA activities. The focus of FDA approvals for new drugs and biological products is the result of Phase III human trials, which are aimed at determining the dose at which a drug is effective. In general, there is not typically a requirement for a manufacturer to demonstrate that a new drug is superior to existing treatments in order to be approved.

FDA Approved Indications

Cosentyx has six FDA-approved indications:

- Adult and pediatric plaque psoriasis (PsO)
- Adult psoriatic arthritis (PsA)
- Ankylosing spondylitis (AS)
- Non-radiographic axial spondyloarthritis (nr-axSpA)
- Pediatric psoriatic arthritis (JPsA) and enthesitis-related arthritis (ERA)
- Hidradenitis suppurativa (HS)

Information below is provided by indication when appropriate.

[3] https://www.nlm.nih.gov/nichsr/hta101/ta10103.html

Supporting Evidence, Clinical Effectiveness, and Cost Effectiveness

Supporting evidence, clinical effectiveness information, and cost effectiveness information was compiled from the sources below. These resources allowed for an efficient review of HTA reports, meta-analyses, and secondary resources developed by established domestic and international organizations. This approach allows for consistent review and leveraging established methodologic processes to assess quality and conclusion of evidence.

- **Cochrane Library**:[4] an organization that prepares systematic reviews and meta-analyses for a range of clinical areas, drug classes, and diseases/conditions. Literature in this appendix was pulled by searching Cochrane Reviews for "secukinumab" and indication and reviewing "Cochrane Reviews" (i.e., not compiling information from Cochrane Protocols, Trials, Editorials, Special Collections, or Clinical Answers).**Institute for Clinical and Economic Review** (ICER):[5] a U.S.-based independent non-profit organization that seeks to place a value on medical care by providing comprehensive clinical and cost-effectiveness analyses of treatments, tests, and procedures. Literature in this appendix was pulled by searching ICER Research Assessments for "secukinumab" and indication. ICER cost-effectiveness recommendations are non-binding for any U.S. federal, state, and local governments.
- **National Institute for Health and Care Excellence** (NICE):[6] a United Kingdom-based governmental institute that provides national guidance and guidelines based on evaluations of efficacy, safety, and cost-effectiveness. Literature in this appendix was pulled by searching published NICE guidance for "secukinumab" and indication.
- **Canadian Agency for Drugs and Technologies in Health** (CADTH):[7] a Canada-based not-for-profit organization responsible for providing health care decision makers with objective evidence to help make informed decisions about the optimal use of health technologies, including providing advice, recommendations, and tools. Literature in this appendix was pulled by searching Health Technology Assessment and Reimbursement Reviews for "secukinumab" and indication. CADTH's recommendations are non-binding for federal, provincial, and territorial public drug plans and provincial cancer agencies (with the exception of Quebec).[8]
- **Institute for Quality and Efficiency in Health Care** (IQWiG):[9] a Germany-based governmental agency responsible for assessing the quality and efficiency of medical treatments, including drugs, non-drug interventions, diagnostic and screening methods, and treatment and disease management. Literature in this appendix was pulled by searching Drug Assessment Projects and Reports for "secukinumab" and indication.
- **International Network of Agencies for Health Technology Assessment** (INAHTA):[10] maintains an **international HTA database** that compiles assessments across jurisdictions. Studies and benefit assessments not already identified from ICER, NICE, CADTH, and IQWiG may be pulled for the Board's review. Only studies with robust English summaries will be summarized in this appendix.

[4] https://www.cochranelibrary.com/
[5] https://icer.org/
[6] https://www.nice.org.uk/
[7] https://www.cadth.ca/
[8] https://www.cadth.ca/cadth-reimbursement-reviews
[9] https://www.iqwig.de/en/
[10] https://database.inahta.org/

Literature that met the above criteria are displayed below and quoted directly, with page numbers for reference, to summarize clinical effectiveness conclusions and cost-effectiveness conclusions. Additional information beyond these conclusions can be found in the literature itself, which is cited.

Priority Populations and QALYs: The Board considered health equity impacts to priority populations of Cosentyx. Please see Appendix H, Appendix J, and Appendix L for more information. Acknowledging that QALYs may discount the value of life because of an individual's disability or age, the Board has noted when studies utilize QALYs below.

Input from Patients and Caregivers, Input from Individuals with Scientific and Medical Training, and Voluntarily Submitted Information

The FDA released an updated Benefit-Risk Assessment for New Drug and Biological Products: Guidance for Industry on October 20, 2023.[11] This guidance states (pp.12-13):

"FDA recognizes the importance of enabling meaningful patient input to inform drug development and regulatory decision-making, including in the context of FDA's benefit-risk assessment. Patients are experts in the experience of their disease or condition, and they are the ultimate stakeholders in the outcomes of medical treatment. Different types of patient experience data can inform nearly every aspect of FDA's benefit-risk assessment."

This appendix provides a robust overview of the scientific studies of clinical and cost effectiveness of Cosentyx, with many of the HTA organizations including patient perspectives in some manner. There is additional information contained in Appendix H: Input from Patients and Caregivers, Appendix I: Input from Individuals with Scientific and Medical Training, and Appendix J: Voluntarily Submitted information which may contain additional patient perspectives of the relative financial effects of Cosentyx on health, medical, and social costs not captured in this appendix. The Board may want to weigh information from all four appendices when evaluating the relative financial effects of Cosentyx.

Plaque Psoriasis (PsO): Adult and Pediatric

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics.[12]

Manufacturer-Reported Benefits

Information contained in Cosentyx's FDA label, Section 14 Clinical Studies, reports on the following studies and the resulting primary and key secondary efficacy analyses.[13]

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[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-assessment-new-drug-and-biological-products

[12] https://pubmed.ncbi.nlm.nih.gov/30772098/

[13] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

Adult Plaque Psoriasis

Four multicenter, randomized, double-blind, placebo-controlled trials of subcutaneous Cosentyx for subjects 18 years of age and older with PsO. In all trials, the endpoints were the proportion of subjects who achieved a reduction in PASI score of at least 75% (PASI 75) from baseline to Week 12 and treatment success (clear or almost clear) on the Investigator's Global Assessment modified 2011 (IGA). The PASI is a composite score that takes into consideration both the percentage of BSA affected and the nature and severity of psoriatic changes within the affected regions.[14]

Figure D-1
Trials PsO1 and PsO2 (Table 3)

	Trial PsO1			Trial PsO2		
	COSENTYX 300 mg (N = 245) n (%)	COSENTYX 150 mg (N = 245) n (%)	Placebo (N = 248) n (%)	COSENTYX 300 mg (N = 327) n (%)	COSENTYX 150 mg (N = 327) n (%)	Placebo (N = 326) n (%)
PASI 75 response	200 (82)	174 (71)	11 (4)	249 (76)	219 (67)	16 (5)
IGA of clear or almost clear	160 (65)	125 (51)	6 (2)	202 (62)	167 (51)	9 (3)

Figure D-1 shows the clinical outcomes of two trials of adults with PsO (subcutaneous treatment) as compared to placebo.

Figure D-2
Trials PsO3 and PsO4 (Table 4)

	Trial PsO3			Trial PsO4		
	COSENTYX 300 mg (N = 59) n (%)	COSENTYX 150 mg (N = 59) n (%)	Placebo (N = 59) n (%)	COSENTYX 300 mg (N = 60) n (%)	COSENTYX 150 mg (N = 61) n (%)	Placebo (N = 61) n (%)
PASI 75 response	44 (75)	41 (69)	0 (0)	52 (87)	43 (70)	2 (3)
IGA of clear or almost clear	40 (68)	31 (53)	0 (0)	44 (73)	32 (52)	0 (0)

Figure D-2 shows the clinical outcomes of two trials of adults with PsO (subcutaneous treatment) as compared to placebo.

Pediatric Plaque Psoriasis

A 52-week, multicenter randomized, double-blind, placebo trial enrolled 162 pediatric subjects 6 years of age and older, with severe plaque psoriasis. Subjects were randomized to receive subcutaneous placebo, Cosentyx, or a biologic active control.

[14] The Psoriasis Area and Severity Index (PASI) score is a tool used by dermatologists to measure the severity of psoriasis and a patient's response to treatment. The PASI score ranges from 0–72, with higher scores indicating greater severity

Figure D-3
Pediatric Trial PsO8 (Table 6)

	Body weight < 50 kg		Body weight ≥ 50 kg		Total	
	COSENTYX 75 mg (N = 22) n (%)	Placebo (N = 20) n (%)	COSENTYX 150 mg (N = 21) n (%)	Placebo (N = 21) n (%)	COSENTYX[a] (N = 43) n (%)	Placebo (N = 41) n (%)
IGA of clear or almost clear	7 (32)	1 (5)	17 (81)	1 (5)	24 (56)	2 (5)
PASI 75 response	12 (55)	2 (10)	18 (86)	4 (19)	30 (70)	6 (15)
PASI 90 response	9 (41)	1 (5)	17 (81)	0 (0)	26 (60)	1 (2)
Non-responder imputation was used to handle missing values. [a]COSENTYX treated subjects received 75 mg for subjects less than 50 kg and 150 mg for subjects at least 50 kg body weight.						

Figure D-3 shows the clinical outcomes in pediatric subjects with severe PsO (subcutaneous treatment) as compared to placebo.

Voluntarily Submitted Manufacturer Information

Novartis voluntarily submitted the following information regarding the financial effects of Cosentyx on health, medical, or social services costs. Information included:

- "The medicine is backed by strong evidence supporting its safety and efficacy for patients across multiple autoimmune diseases, including moderate to-severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS) and radiographic axial spondyloarthritis (nr-axSpA)."
- "Cosentyx is indicated for the treatment of moderate-to-severe plaque psoriasis in patients 6 years of age and older who are candidates for systemic therapy or phototherapy. Cosentyx is also indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older."
- "In clinical trials, Cosentyx has been shown to help achieve clear skin in plaque psoriasis"
- "A health economic model was developed to demonstrate the cost-effectiveness of Cosentyx for patients with plaque psoriasis. The patient population of interest included adults diagnosed with moderate-to-severe plaque psoriasis who are candidates for systemic or biologic therapy. The model demonstrated that the cost per responder was lower for Cosentyx 150 mg and 300 mg than some leading therapeutic alternatives."

Table D-1
Plaque Psoriasis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
Cochrane	***Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis: 2023***[15] For reaching PASI 90, the most effective drugs when compared to placebo were (SUCRA rank order, all high-certainty evidence): infliximab (risk ratio (RR) 49.16, 95% CI 20.49 to 117.95), bimekizumab (RR 27.86, 95% CI 23.56 to 32.94), ixekizumab (RR 27.35, 95% CI 23.15 to 32.29), risankizumab (RR 26.16, 95% CI 22.03 to 31.07). Clinical effectiveness of these drugs was similar when compared against each other. Bimekizumab and ixekizumab were significantly more likely to reach PASI 90 than **secukinumab**. Bimekizumab, ixekizumab, and risankizumab were significantly more likely to reach PASI 90 than brodalumab and guselkumab. Infliximab, anti-IL17 drugs (bimekizumab, ixekizumab, **secukinumab**, and brodalumab), and anti-IL23 drugs except tildrakizumab were significantly more likely to reach PASI 90 than ustekinumab, three anti-TNF alpha agents, and deucravacitinib. Ustekinumab was superior to certolizumab. Adalimumab, tildrakizumab, and ustekinumab were superior to etanercept. No significant difference was shown between apremilast and two non-biological drugs: ciclosporin and methotrexate. We found no significant difference between any of the interventions and the placebo for the risk of SAEs. The risk of SAEs was significantly lower for participants on methotrexate compared with most of the interventions. Nevertheless, the SAE analyses were based on a very low number of events with very low- to moderate-certainty evidence for all the comparisons. The findings therefore have to be viewed with caution. For other efficacy outcomes (PASI 75 and Physician Global Assessment (PGA) 0/1), the results were similar to the results for PASI 90. Information on quality of life was often poorly reported and was absent for several of the interventions.	Not applicable.
ICER	***Comparative effectiveness of targeted immunomodulators for the treatment of moderate-to-severe plaque psoriasis: A systematic review and network meta-analysis***[16]	***Cost-Effectiveness of Targeted Pharmacotherapy for Moderate to Severe Plaque Psoriasis: 2016***[17] The incremental benefits compared with no targeted treatment were, in

[15] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011535.pub6/full?highlightAbstract=plaque%7Cplaqu%7Cpsoriasi%7Cpsoriasis%7Csecukinumab

[16] https://icer.org/news-insights/journal-articles/comparative-effectiveness-of-targeted-immunomodulators-for-the-treatment-of-moderate-to-severe-plaque-psoriasis-a-systematic-review-and-network-meta-analysis/

[17] https://icer.org/news-insights/journal-articles/psoriasis/ - QALY used in literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	In the network meta-analysis, the targeted immunomodulators ordered by increasing relative risk (demonstrating greater likelihood) of achieving a 75% improvement on the Psoriasis Area and Severity Index relative to placebo were as follows: apremilast (6.2), etanercept (9.6), adalimumab (13.0), ustekinumab (14.0), **secukinumab** (15.4), infliximab (16.2), brodalumab (17.3), and ixekizumab (17.9). Ixekizumab, brodalumab, and infliximab were all statistically superior to ustekinumab, adalimumab, etanercept, and apremilast; results were similar to those of head-to-head studies where data were available. Limitations: Much of the evidence is short-term (covering 10-16 weeks); limited direct comparisons. Conclusions: The interleukin 17A inhibitors are more effective in achieving clearance than ustekinumab, and they are generally more effective than etanercept, adalimumab, and apremilast.	descending order: ixekizumab 1.68 QALYs (95% credible range [CR] = 1.11-2.02), brodalumab 1.64 QALYs (95% CR = 1.08-1.98), **secukinumab** 1.51 QALYs (95% CR = 1.00-1.83), ustekinumab 1.43 QALYs (95% CR=0.94-1.74), infliximab 1.27 QALYs (95% CR=0.89-1.55), adali- mumab 1.15 QALYs (95% CR = 0.76-1.44), etanercept 0.97 QALYs (95% CR = 0.61-1.25), and apremilast 0.87 QALYs (95% CR = 0.52-1.17). Costs of care without targeted treatment totaled $66,451, and costs of targeted treatment ranged from $137,080 (apremilast) to $255,422 (ustekinumab). Probabilistic sensitivity analysis results indicated that infliximab and apremilast are likely to be the most cost-effective initial treatments at willingness-to-pay thresholds around $100,000 per QALY, while IL-17 drugs are more likely to be cost-effective at thresholds approaching $150,000 per QALY. Acquisition cost of the initial targeted drug and utility of clinical response were the most influential parameters. Our findings suggest that initial targeted treatment with IL-17 inhibitors is the most effective treatment strategy for plaque psoriasis patients who have failed methotrexate and phototherapy. Apremilast, brodalumab, infliximab, ixekizumab, and **secukinumab** are cost-effective at different willingness-to-pay thresholds. Additional research is needed on whether the effectiveness of targeted agents changes when used after previously targeted agents. ***Institute for Clinical and Economic Review's Updated Assessment of New Targeted Therapies for Plaque Psoriasis Notes Minor Distinctions in Effectiveness, While Recent Price Hikes Have Made Entire Drug Class Less Cost-Effective***[18] Findings on the clinical effectiveness of drugs included in ICER's 2016 review remains largely unchanged, except in comparisons of **secukinumab** to adalimumab and ustekinumab. In both instances, the evidence rating of **secukinumab** improved due to the emergence of new data.
NICE	***Secukinumab for treating moderate to severe plaque psoriasis in children and young people: 2021***[19] **Secukinumab** is more effective than etanercept: The trial showed that people having **secukinumab** had a higher PASI response rate (PASI 75, that is, a 75% reduction in PASI score from baseline) compared with placebo and etanercept at week 12. The trial also showed that, at week 52, the higher response rates were sustained.	***Secukinumab for treating moderate to severe plaque psoriasis in children and young people: 2021***[21] The total costs for **secukinumab** are similar to or lower than those for ustekinumab, etanercept and adalimumab: The company presented a cost-comparison analysis that modeled the total costs of **secukinumab**, ustekinumab and etanercept over 5 years. To determine the proportion of people who continue treatment, it took into account stopping treatment based on PASI 75 response rates.

[18] https://icer.org/news-insights/press-releases/psoriasis-update/ - QALY used in literature.
[19] https://www.nice.org.uk/guidance/ta734/chapter/3-Committee-discussion- QALY used in literature.
[21] https://www.nice.org.uk/guidance/ta734/chapter/3-Committee-discussion

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	Secukinumab has a similar effectiveness to ustekinumab: To provide a comparison of effectiveness with ustekinumab, the company produced network meta-analyses using a fixed-effect model with data from 4 clinical trials. The model provided PASI response rates and Children's Dermatology Life Quality Index scores comparing **secukinumab** with etanercept, ustekinumab and placebo. ***Secukinumab for treating moderate to severe plaque psoriasis 2015***[20] **Secukinumab** is recommended, within its marketing authorisation, as an option for treating adults with plaque psoriasis only when: • the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 • the disease has failed to respond to standard systemic therapies, for example, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation), or these treatments are contraindicated or the person cannot tolerate them The company included 5 relevant international, multicentre, phase 3, double-blind, randomised, controlled trials. The Committee agreed that the company had included relevant, high-quality trials. The Committee agreed that secukinumab was clinically superior to both placebo and etanercept for all primary and secondary outcomes.	***Secukinumab for treating moderate to severe plaque psoriasis 2015***[22] The Committee agreed that it was difficult to determine a most plausible incremental cost-effectiveness ratio (ICER) because of the structural and parameter uncertainties in the model. It agreed that the ICERs ranging from approximately £17,700 per QALY gained (compared with ustekinumab 90 mg) to £42,400 per QALY gained (compared with etanercept) were probably overestimated because the model had not accounted for PASI 100 responses nor the disutility values associated with best supportive care. The Committee considered that the ICERs compared with the biological treatments ranged from approximately £17,700 per QALY gained (compared with ustekinumab 90 mg) to £42,400 per QALY gained (compared with etanercept). The Committee concluded that these ICERs were probably overestimated because of the short time horizon, and because the model had not accounted for PASI 100 responses nor the disutility values associated with best supportive care. Considering the patient access scheme price of secukinumab, the clinical data, and the testimony of the experts, the Committee concluded that the most plausible ICER was likely to be in line with the other biologicals already recommended in previous NICE guidance.
CADTH	***Newer Biologics for the Treatment of Plaque Psoriasis: 2021***[23] Newer biologics such as secukinumab, ixekizumab, brodalumab and risankizumab were more favourable compared to older biologics (adalimumab, etanercept, and ustekinumab) in reaching 90% or 100% skin clearance, as measured with the Psoriasis Area Severity Index. The risk of side effects was similar between the newer and older biologics. No relevant direct comparative evidence regarding **secukinumab** and adalimumab was identified for the outcome PASI 90. Indirect evidence from 4 NMAs found that **secukinumab** was favourable to adalimumab in reaching a PASI 90 response with short-term treatment. Direct evidence from 1 RCT found that the likelihood of achieving a PASI 90 response was statistically significantly higher in the **secukinumab** group compared to the etanercept group. Indirect evidence from 4 NMAs suggested that **secukinumab** was favourable to etanercept in reaching PASI 90 with short-term treatment.	Not applicable.

[20] https://www.nice.org.uk/guidance/ta350/chapter/4-Consideration-of-the-evidence - QALY used in literature.
[22] https://www.nice.org.uk/guidance/ta350/chapter/4-Consideration-of-the-evidence - QALY used in literature.
[23] https://www.cadth.ca/sites/default/files/pdf/htis/2021/RC1377%20Biologics%20for%20plaque%20psoriasis%20Final.pdf

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	Direct evidence from 2 RCTs found that the likelihood of achieving a PASI 90 response was statistically significantly higher in the **secukinumab** group compared to the ustekinumab group. Four systematic reviews with NMA reported indirect comparative results of **secukinumab** versus ustekinumab. **Secukinumab** was favourable to ustekinumab (all doses) in reaching PASI 90 with short-term treatment.	
IQWiG	***Secukinumab (plaque psoriasis) - Benefit assessment according to §35a Social Code Book V - 2017***[24] The aim of the present report was to assess the added benefit of secukinumab in comparison with the appropriate comparator therapy (ACT) [Fumaric acid esters or ciclosporin or methotrexate or phototherapy] in adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy and/or phototherapy. In the overall consideration, there were only positive effects for secukinumab in comparison with fumaric acid esters. The positive effects included an indication of considerable added benefit in the category “morbidity” for the outcome “remission” (PASI 100). In addition, there was a hint of a major added benefit in the category “health-related quality of life” for the outcome “DLQI (0 or 1)”. There were further positive effects in the category “non-serious/non-severe side effects”. For the outcome “discontinuation due to AEs”, there was an indication of lesser harm of considerable extent for patients < 65 years and a hint of lesser harm of non-quantifiable extent for patients ≥ 65 years. There was an indication of lesser harm of considerable extent for each of the outcomes “gastrointestinal disorders” and “flushing”. For the outcome “blood and lymphatic system disorders”, there was a hint of lesser harm of considerable extent. In summary, there is an indication of considerable added benefit of secukinumab in comparison with the ACT fumaric acid esters for patients with moderate to severe plaque psoriasis who are candidates for systemic therapy and/or phototherapy.	Not applicable.

[24] https://www.iqwig.de/download/a17-08_secukinumab_extract-of-dossier-assessment_v1-0.pdf

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the evidence reviews above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available.

Table D-2
ClinicalTrials.Gov Completed Phase III and IV Studies Summary

Study Name	Results
Outcome of Treatment With Secukinumab in the Treatment of Moderate to Severe Plaque Psoriasis at Tertiary Care Hospital[25]	Not applicable.
Plaque Psoriasis Efficacy and Safety With Secukinumab (OPTIMISE): 2019[26]	Standard every 4 week (q4w) dosing of **secukinumab** 300 mg is the optimal regimen to achieve and maintain clear or almost clear skin at week 52; the majority of the patients (85·7%) maintain PASI 90 at week 52. Superiority of intensified (q2w) dosing over the q4w regimen could not be claimed. However, patients with a higher body weight (≥ 90 kg) not achieving PASI 90 response at week 24 may benefit from q2w dosing.[27]
Study of Secukinumab Compared to Ustekinumab in Subjects With Plaque Psoriasis (CLARITY): 2021[28]	This second head-to-head study confirmed the superior efficacy of **secukinumab** over ustekinumab in skin clearance and quality of life through 52 weeks, with safety comparable to that reported in previous trials.[29]
Open-label Study of Subcutaneous Secukinumab to Evaluate Efficacy and Safety in Patients With Plaque Psoriasis Who Had Inadequate Response to Cyclosporine A: 2017[30]	Not applicable.

Adult Psoriatic Arthritis (PsA)

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis.[31]

[25] https://clinicaltrials.gov/study/NCT05891964?cond=Plaque%20Psoriasis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=1
[26] https://clinicaltrials.gov/study/NCT02409667?cond=Plaque%20Psoriasis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=2
[27] https://pubmed.ncbi.nlm.nih.gov/31102257/
[28] https://clinicaltrials.gov/study/NCT02826603?cond=Plaque%20Psoriasis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=4
[29] https://pubmed.ncbi.nlm.nih.gov/32365251/
[30] https://clinicaltrials.gov/study/NCT02547714?cond=Plaque%20Psoriasis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=6
[31] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.40726

Manufacturer-Reported Benefits

Information contained in Cosentyx's FDA label, Section 14 Clinical Studies, reports on the following studies and the resulting primary and key secondary efficacy analyses.[32] The safety and efficacy of Cosentyx was assessed in 3 randomized, double-blind, placebo controlled trials (PsA1, PsA2, and PsA3) in adult patients, age 18 years and older with active PsA (greater than or equal to 3 swollen and greater than or equal to 3 tender joints) despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. Patients in these trials had a diagnosis of PsA of at least 5 years across all trials.

Figure D-4

Adult PsA1 Study: Subcutaneous Treatment (Table 7)

	COSENTYX 150 mg (N = 100)	COSENTYX 300 mg (N = 100)	Placebo (N = 98)	Difference from placebo (95% CI)	
				COSENTYX 150 mg	COSENTYX 300 mg
ACR20 response					
Week 16 (%)	60	57	18	42 (30, 54)	38 (26, 51)
Week 24 (%)	51	54	15	36 (24, 48)	39 (27, 51)
ACR50 response					
Week 16 (%)	37	35	6	31 (21, 42)	28 (18, 39)
Week 24 (%)	35	35	7	28 (18, 38)	28 (17, 38)
ACR70 response					
Week 16 (%)	17	15	2	15 (7, 23)	13 (5, 20)
Week 24 (%)	21	20	1	20 (12, 28)	19 (11, 27)

Figure D-4 shows the percentage of adult patients who achieved an ACR20 response by visit. Patients on placebo who received Cosentyx without a loading regimen achieved similar ACR20 responses over time.

[32] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

Figure D-5
Adult PSA1 Study: Subcutaneous Treatment (Table 8)

	COSENTYX 150 mg (N = 100)	COSENTYX 300 mg (N = 100)	Placebo (N = 98)
Number of swollen joints			
Baseline	12.0	11.2	12.1
Mean change at Week 16	-4.86	-5.83	-3.22
Number of tender joints			
Baseline	24.1	20.2	23.5
Mean change at Week 16	-10.70	-10.01	-1.77
Patient's assessment of pain			
Baseline	58.9	57.7	55.4
Mean change at Week 16	-22.91	-23.97	-7.98
Patient global assessment			
Baseline	62.0	60.7	57.6
Mean change at Week 16	-25.47	-25.40	-8.25
Physician global assessment			
Baseline	56.7	55.0	55.0
Mean change at Week 16	-29.24	-34.71	-14.95
Disability index (HAQ)			
Baseline	1.2200	1.2828	1.1684
Mean change at Week 16	-0.45	-0.55	-0.23
CRP (mg/L)			
Baseline	14.15	10.88	7.87
Mean change at Week 16[b]	-8.41	-7.21	0.79

Figure D-5 shows the improvements in the components of the American College of Rheumatology (ACR) response criteria in the adult PsA1 study.

Radiographic Response: Inhibition of progression of structural damage was assessed radiographically at Week 24 compared to baseline. Treatment with subcutaneous Cosentyx 150 mg without a loading dose, 150 mg with a loading dose and 300 mg with a loading dose significantly inhibited progression of peripheral joint damage compared with treatment with placebo.

Physical Function: Improvement in physical function as assessed by Health Assessment Questionnaire-Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved at least -0.3 improvement in HAQ-DI score from baseline was greater in the subcutaneous Cosentyx 150 mg and 300 mg groups compared to the placebo group.

Voluntarily Submitted Manufacturer Information

Novartis voluntarily submitted the following information regarding the financial effects of Cosentyx on health, medical, or social services costs. Information included:

- "The medicine is backed by strong evidence supporting its safety and efficacy for patients across multiple autoimmune diseases, including moderate to-severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS) and radiographic axial spondyloarthritis (nr-axSpA)."
- "In clinical trials, Cosentyx has been shown to help achieve clear skin in plaque psoriasis and help stop progressive joint damage and improve physical function in patients with psoriatic arthritis."
- "A health economic model explored the cost-effectiveness of Cosentyx for patients with psoriatic arthritis (PsA). The patient population of interest included adults diagnosed with PsA who are candidates for biologic therapy or apremilast. Cosentyx 150 mg and 300 mg had a lower cost per responder than some leading therapeutic alternatives."

Table D-3
Adult Psoriatic Arthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
NICE	***Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs - 2017***[33] The committee mainly considered the clinical effectiveness evidence from the trials identified for certolizumab pegol (RAPID-PsA) and secukinumab (FUTURE 2). The committee considered the results of the network meta-analysis done by the assessment group. It noted that separate analyses were done for each outcome for patients who had had biological therapy, and for patients who had not had biological therapy to acknowledge the difference in efficacy response in both subpopulations. The committee concluded that although there were limitations in the analyses, it considered that certolizumab pegol and secukinumab were similar to TNF-alpha inhibitors in improving joint symptoms in both biological-naive and biological-experienced subpopulations. The committee noted that treatment with certolizumab pegol and secukinumab resulted in statistically significant	***Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs - 2017***[34] The committee concluded that secukinumab is cost effective in 3 subpopulations (patients who had at least 2 previous DMARDs and no biological therapy, and patients who have had TNF-alpha inhibitors whose disease has not responded to TNF-alpha inhibitors within the first 12 weeks or has stopped responding after 12 weeks, and patients in whom TNF-alpha inhibitors are contraindicated) with ICERs below, or close to, £20,000 per QALY gained only when taking into account the patient access scheme for secukinumab.

[33] https://www.nice.org.uk/guidance/ta445/chapter/4-Committee-discussion - QALY used in literature.
[34] https://www.nice.org.uk/guidance/ta445/chapter/4-Committee-discussion - QALY used in literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
	improvements in health-related quality-of-life measures and in improvements in extra-articular manifestations such dactylitis (that is, inflammation of the fingers or toes) and enthesitis (that is, inflammation of tendons or ligaments).	
IQWiG	***Secukinumab (psoriatic arthritis) - Benefit assessment according to §35a Social Code Book V - 2021***[35] The aim of the…report is the assessment of the added benefit of secukinumab, alone or in combination with methotrexate, in comparison with the appropriate comparator therapy (ACT) in adult patients with active psoriatic arthritis who have responded inadequately to DMARD therapy. In the overall consideration of the data, there is a positive effect of secukinumab in comparison with adalimumab. This effect is present for adult patients with active psoriatic arthritis aged < 65 years and with concomitant moderate to severe plaque psoriasis for the outcome "skin symptoms (PASI 100)". Overall…there is a hint of considerable added benefit of secukinumab in comparison with adalimumab for adult bDMARD-naive patients with active psoriatic arthritis aged < 65 years and with concomitant moderate to severe plaque psoriasis who have responded inadequately to previous DMARD therapy. An added benefit of secukinumab in comparison with adalimumab is not proven for adult bDMARD-naive patients with active psoriatic arthritis aged ≥ 65 years and with concomitant moderate to severe plaque psoriasis who have responded inadequately to previous DMARD therapy. The company presented no data for the assessment of the added benefit of secukinumab, alone or in combination with methotrexate, in comparison with the ACT for patients with active psoriatic arthritis who have responded inadequately to previous bDMARD therapy. An added benefit of secukinumab, alone or in combination with methotrexate, is not proven for these patients.	Not applicable.

[35] https://www.iqwig.de/download/a21-01_secukinumab_addendum-to-commission-a20-80_v1-0.pdf

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available.

Table D-4
ClinicalTrials.Gov Completed Phase III and IV Studies Summary

Study Name	Results
24 Week Efficacy and 3-year Safety and Efficacy of Secukinumab in Active Psoriatic Arthritis: 2019[36]	**Secukinumab** provided sustained improvements in signs and symptoms in active PsA patients through 52 weeks. High acceptability of autoinjector was observed. The safety profile was consistent with that reported previously., 2018[37]
Study to Demonstrate the Efficacy, Safety and Tolerability of Intravenous Secukinumab up to 52 Weeks in Subjects With Active Psoriatic Arthritis (INVIGORATE 2): 2024[38]	IV SEC (6 mg/kg at baseline followed by 3 mg/kg q4w) was safe and effective for the long-term treatment of active PsA. Treatment responses were maintained up to Week 52 for patients randomized to IV SEC. For patients originally randomized to PBO who switched to receive IV SEC at Week 16, an increase in efficacy responses comparable to those in patients randomized to IV SEC was observed up to Week 52. Safety was consistent with the known safety profile of subcutaneous SEC, and no new safety signals were observed., 2023[39]
Study of Power Doppler Ultrasound (PDUS) to Measure Response of Secukinumab Treatment in Patients With Active Psoriatic Arthritis (PsA) (PDUS): 2021[40]	This unique ultrasound study shows that apart from improving the signs and symptoms of PsA, IL-17A inhibition with **secukinumab** leads to a rapid and significant reduction of synovitis in PsA patients.[41]

[36] https://clinicaltrials.gov/study/NCT01989468?cond=Psoriatic%20Arthritis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=3
[37] https://pubmed.ncbi.nlm.nih.gov/29544534/
[38] https://clinicaltrials.gov/study/NCT04209205?cond=Psoriatic%20Arthritis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=4
[39] https://acrabstracts.org/abstract/efficacy-and-safety-of-intravenous-secukinumab-for-the-treatment-of-active-psoriatic-arthritis-16-and-52-week-results-from-a-randomized-double-blind-phase-3-study/
[40] https://clinicaltrials.gov/study/NCT02662985?cond=Psoriatic%20Arthritis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=7
[41] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9071547/

Ankylosing Spondylitis (AS)

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis.[42]

Manufacturer-Reported Benefits

Information contained in Cosentyx's FDA label, Section 14 Clinical Studies, reports on the following studies and the resulting primary and key secondary efficacy analyses.[43] The safety and efficacy of subcutaneous Cosentyx were assessed in adult patients (18 years of age and older) with active AS in three randomized, double-blind, placebo-controlled trials.

Figure D-6
Study AS1: Subcutaneous Treatment (Table 10)

	COSENTYX 150 mg (n = 72)	Placebo (n = 74)	Difference from placebo (95% CI)
ASAS20 response, %	61	28	33 (18, 48)
ASAS40 response, %	36	11	25 (12, 38)

Figure D-6 shows improvements in the ASAS20 and ASAS40 response (indicating a minimum of 20% or 40% improvement from baseline in at least 3 of the following domains: patient global, total back pain, function, and inflammation) in patients taking subcutaneous Cosentyx.

[42] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.41042
[43] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

Figure D-7
AS1 Study: Subcutaneous Treatment (Table 11)

	COSENTYX 150 mg (N = 72)		Placebo (N = 74)	
	Baseline	**Week 16 change from baseline**	**Baseline**	**Week 16 change from baseline**
ASAS20 response criteria				
-Patient Global Assessment of Disease Activity (0-100 mm)[1]	67.5	-27.7	70.5	-12.9
-Total spinal pain (0-100 mm)	66.2	-28.5	69.2	-10.9
-BASFI (0-10)[2]	6.2	-2.2	6.1	-0.7
-Inflammation (0-10)[3]	6.5	-2.5	6.5	-0.8
BASDAI score[4]	6.6	-2.2	6.8	-0.9
BASMI[5]	3.6	-0.51	3.9	-0.22
hsCRP[6] (mg/L) mean change at Week 16	27.0	-17.2	15.9	0.8

1. Percent of subjects with at least a 20%- and 10-unit improvement measured on a Visual Analog Scale (VAS) with 0 = none, 100 = severe.
2. Bath Ankylosing Spondylitis Functional Index.
3. Inflammation is the mean of two patient-reported stiffness self-assessments in BASDAI.
4. Bath Ankylosing Spondylitis Disease Activity Index.
5. Bath Ankylosing Spondylitis Metrology Index.
6. High sensitivity C-reactive protein / mean change based upon observed data.

Table D-7 shows improvements in the main components of the ASAS20 response criteria: patient global assessment of disease activity, back pain, patient functional index, and various inflammation measures.

Figure D-8
AS3 Study: Subcutaneous Treatment (Figure 3)

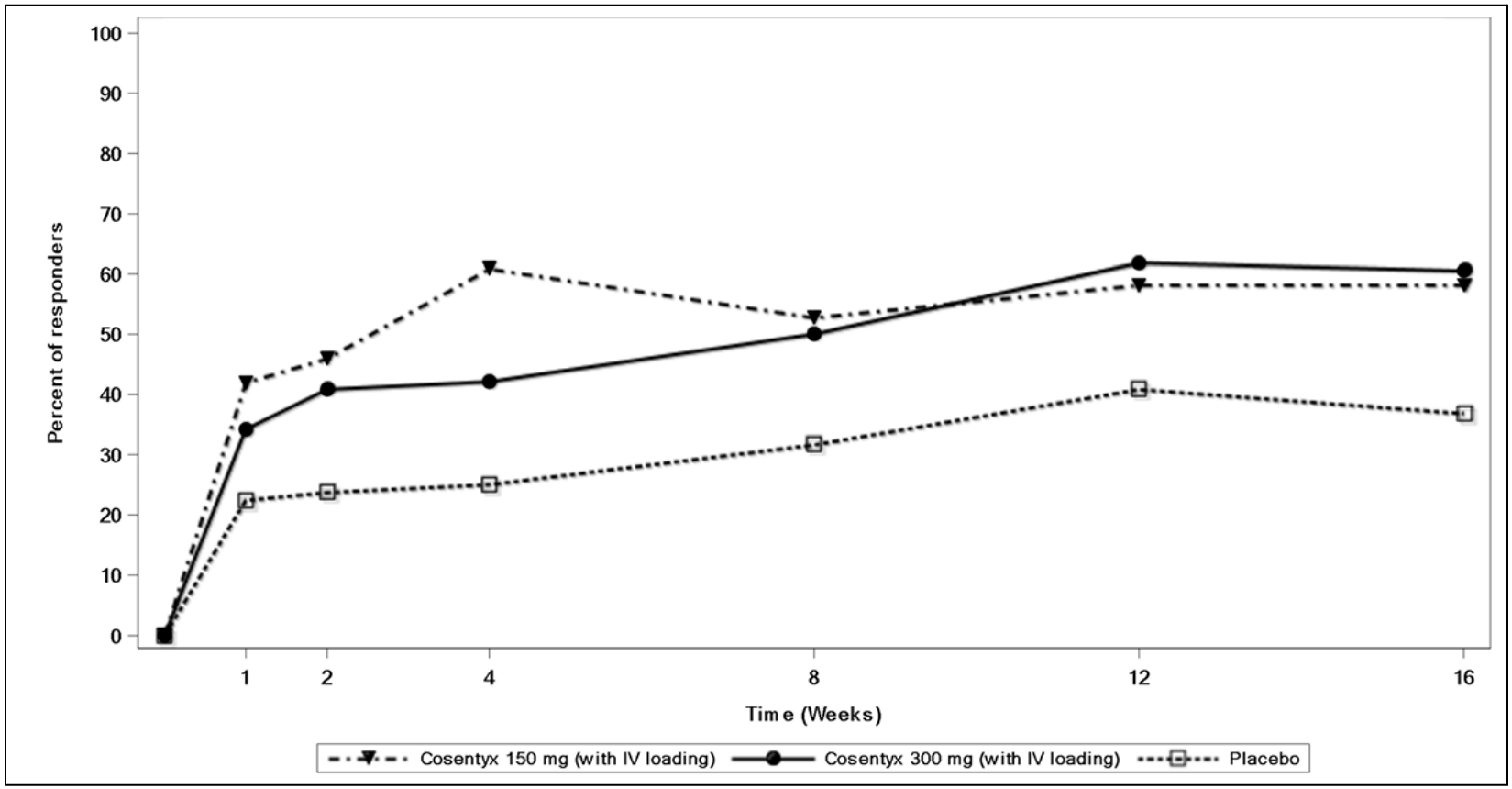

Figure D-8 shows the percent of patients achieving ASAS20 responses by visit.

Voluntarily Submitted Manufacturer Information

Novartis voluntarily submitted the following information regarding the financial effects of Cosentyx on health, medical, or social services costs. Information included:

- "The medicine is backed by strong evidence supporting its safety and efficacy for patients across multiple autoimmune diseases, including moderate to-severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS) and radiographic axial spondyloarthritis (nr-axSpA)."
- "A health economic model explored the cost-effectiveness of Cosentyx for patients. The patient population of interest included adults with active AS treated with a biologic. The cost per responder was lower for Cosentyx 150 mg than another leading therapeutic alternative."

Table D-5
Ankylosing Spondylitis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
NICE	***Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors: 2016***[44] The committee noted that a patient organisation submission included a survey of several hundred patients with AS, which summarised the major effect that the disease has on people's health and quality of life. The committee concluded that the availability of an effective new treatment option would be valuable for people with active AS. The MEASURE 1 and MEASURE 2 trials, which compared secukinumab with placebo in active AS, were conducted across international sites. The committee concluded that **secukinumab** was associated with a statistically significant improvement, compared with placebo, for the disease outcomes included in MEASURE 1 and 2. The company did a network meta-analysis to estimate the relative effectiveness of secukinumab 150 mg and the relevant comparator therapies in a mixed population of patients with AS that had been treated with a biologic agent before (biologic-experienced) or had not (biologic-naive). The committee concluded that secukinumab has a similar efficacy to the TNF-alpha inhibitors.	***Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors: 2016***[45] Based on the analyses presented by the company and ERG, the committee concluded that secukinumab was less expensive and resulted in a similar number of QALYs to the TNF-alpha inhibitors in people with AS that had not been treated with a biologic agent before. In the biologic-experienced population, the committee noted that the ICER for secukinumab compared to conventional care was £2,245 per QALY gained in the company base case and was similar in the ERG's exploratory base case (£2,223 per QALY gained). The committee concluded that **secukinumab** was less expensive and resulted in a similar number of QALYs to the TNF-alpha inhibitors in people with AS that had not been treated with a biologic agent before. The committee concluded that **secukinumab** could be considered a cost-effective use of NHS resources for people with AS that has not been previously treated with TNF-alpha inhibitors.
INAHTA: Argentina Institute for Clinical Effectiveness and Health Policy (IECS)	***Biologics in patients with spondyloarthritis: 2017***[46] Moderate-quality evidence shows that adalimumab, etanercept, infliximab, certolizumab, golimumab (antitumor necrosis factor-alpha, anti-TNF) and **secukinumab** are effective in controlling active ankylosing spondylitis in adults with inadequate response or intolerance to non-steroidal anti-inflammatory drugs (NSAIDs).	Not applicable.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available.

[44] https://www.nice.org.uk/guidance/ta407
[45] https://www.nice.org.uk/guidance/ta407 - QALY used in literature.
[46] https://database.inahta.org/article/19922

Table D-6
ClinicalTrials.Gov Completed Phase III and IV Studies Summary

Study Name	Results
16 Week Efficacy and 2 Year Long Term Safety and Efficacy of Secukinumab in Patients With Active Ankylosing Spondylitis (MEASURE 1): 2017[47]	Our findings indicate that **secukinumab** provides significant and sustained improvements in patient-reported disease activity and health-related quality of life, and reduces functional impairment, fatigue, and impact of disease on work productivity in patients with active AS., 2016[48]
Effect of Secukinumab on Radiographic Progression in Ankylosing Spondylitis as Compared to GP2017 (Adalimumab Biosimilar) (SURPASS): 2023[49]	Spinal radiographic progression over two years was low with no significant difference between **secukinumab** and SDZ-ADL arms. The safety of both treatments was consistent with previous reports.[50]

Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis.[51]

Manufacturer-Reported Benefits

Information contained in Cosentyx's FDA label, Section 14 Clinical Studies, reports on the following one studies and the resulting primary and key secondary efficacy analyses.[52] The safety and efficacy of COSENTYX were assessed in adult patients (18 years of age and older) with active nraxSpA in one randomized, double-blind, placebo-controlled Phase 3 study.

[47] https://clinicaltrials.gov/study/NCT01358175?cond=Ankylosing%20Spondylitis%5C(AS%5C)&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=2
[48] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.39805
[49] https://clinicaltrials.gov/study/NCT03259074?cond=Ankylosing%20Spondylitis%5C(AS%5C)&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=4
[50] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.42852
[51] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.41042
[52] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

Figure D-9

Nr-axSpA1 Study: Subcutaneous Treatment (Table 12)

Number of subjects with ASAS40 response (%)	COSENTYX 150 mg without load (n = 184)	COSENTYX 150 mg with load (n = 185)	Placebo (n = 186)	Difference from placebo (95% CI)	
				COSENTYX 150 mg without load	COSENTYX 150 mg with load
Week 16	75 (41)	74 (40)	52 (28)	13 (3, 22)	12 (2, 22)
Week 52	70 (38)	62 (34)	36 (19)	19 (10, 28)	14 (5, 23)

Difference in proportions with 95% CI based on normal approximation.

Figure D-9 shows the results of nr-axSpA1 Study 1 and improvements in measure of disease activity compared to treatment with placebo.

Figure D-10

Nr-axSpA1 Study: Subcutaneous Treatment (Table 13)

	COSENTYX 150 mg without loading dosage (N = 184)		COSENTYX 150 mg with a loading dosage (N = 185)		Placebo (N = 186)	
	Baseline	Week 16 change from baseline	Baseline	Week 16 change from baseline	Baseline	Week 16 change from baseline
ASAS40 response criteria						
-Patient Global Assessment of Disease Activity (0-100 mm)	71.0	-26.2	72.6	-24.1	68.8	-13.8
-Total back pain (0-100 mm)	72.0	-25.5	73.3	-25.0	70.9	-15.6
-BASFI (0-10)	5.9	-1.6	6.2	-1.8	5.9	-1.0
-Inflammation (0-10)	6.8	-2.8	7.2	-2.8	6.6	-1.7
hsCRP (mg/L) mean change at Week 16	9.8	-4.7	13.4	-7.9	9.2	-2.4
BASDAI (0-10)	6.9	-2.4	7.1	-2.4	6.8	-1.5
-Spinal pain	7.6	-3.0	7.8	-3.0	7.5	-2.0
-Peripheral pain and swelling (0-10)	6.6	-2.4	6.3	-2.3	6.1	-1.6
BASMI	2.8	-0.3	2.9	-0.3	2.8	-0.1

Figure D-10 shows the results of the main components of the ASAS40 response criteria in the nr-axSpA1 Study 1.

Health-Related Quality of Life: Cosentyx treated patients showed improvement in both loading and without loading dosage arms compared to placebo-treated patients in health-related quality of life assessments.

Voluntarily Submitted Manufacturer Information

Novartis voluntarily submitted the following information regarding the financial effects of Cosentyx on health, medical, or social services costs. Information included:

- "The medicine is backed by strong evidence supporting its safety and efficacy for patients across multiple autoimmune diseases, including moderate to-severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS) and radiographic axial spondyloarthritis (nr-axSpA)."
- "The economic impact of work limitations related to nr-axSpA is substantial and compounded by the typically young age at diagnosis. Patients treated with Cosentyx showed substantial reduction in work-related impairment, measured through mean change in the Work Productivity and Activity Impairment (WPAI) from baseline to Week 52."

Table D-7
Non-Radiographic Axial Spondyloarthritis Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
NICE	***Secukinumab for treating non-radiographic axial spondyloarthritis: 2021***[53] **Secukinumab** increases the proportion of people having an ASAS 40 response compared with placebo when used as first-line treatment. There are limited clinical-effectiveness data for **secukinumab** used after a TNF-alpha inhibitor, but it is likely to be effective	***Secukinumab for treating non-radiographic axial spondyloarthritis: 2021***[54] The committee concluded that **secukinumab** had fewer QALYs in all the company and ERG's analyses. The committee noted that in analyses where the cost of biosimilar adalimumab is assumed for all TNF-alpha inhibitors, the costs of **secukinumab** were also higher than TNF-alpha inhibitors. For the full population covered by the marketing authorisation, the committee did not consider **secukinumab** to be cost effective compared with TNF-alpha inhibitors for treating non-radiographic axial spondyloarthritis. Compared with conventional care [in the whole population], secukinumab gave incremental cost-effectiveness ratios (ICERs) of: • £5,413 per QALY gained in the company base case (with modelling errors corrected by the ERG) • £8,399 per QALY gained in the ERG exploratory base case • £7,727 per QALY gained using the ERG exploratory base-case assumptions but assuming common baselines • £19,421 per QALY gained in the ERG exploratory base case for second-line treatments. There were no data to determine if these results would be different in the

[53] https://www.nice.org.uk/guidance/ta719/chapter/3-Committee-discussion - QALY used in literature.
[54] https://www.nice.org.uk/guidance/ta719/chapter/3-Committee-discussion - QALY used in literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
		subgroup of people who cannot have TNF-alpha inhibitors or whose condition had not responded to a TNF-alpha inhibitor. However, given the ICERs were lower than £20,000 compared with conventional care in the whole population, it was reasonable to consider secukinumab a cost-effective use of NHS resources for people who would otherwise have conventional care.Conclusion: **Secukinumab** is likely to be cost effective only if TNF-alpha inhibitors do not work or are not suitable, so it is recommended in these situations
INAHTA: Singapore Agency for Care Effectiveness (ACE)	***Ixekizumab and secukinumab for treating active non-radiographic axial spondyloarthritis: 2023***[55] The Committee reviewed available clinical evidence from 2 phase III, double-blind randomised controlled trials (RCTs) comparing ixekizumab [Taltz] (COAST-X) or **secukinumab** (PREVENT) with placebo among patients with active nr-axSpA. The Committee heard that at week 16 of these RCTs, both ixekizumab and **secukinumab** were associated with statistically significant improvements in the proportion of patients who achieved the Assessment of SpondyloArthritis international Society 40% response criteria (ASAS40) and a significantly increased proportion of patients who achieved a 50% improvement in BASDAI score (BASDAI50), compared with placebo. The Committee noted that both IL-17 inhibitors were generally well-tolerated in the trials and had acceptable safety profiles. While ixekizumab and **secukinumab** were associated with higher rates of treatment-emergent adverse events compared with placebo, most of these events were reported to be mild-to-moderate in severity. In the absence of head-to-head RCTs comparing both IL-17 inhibitors with each other, the Committee acknowledged the results of indirect comparisons and network meta-analyses considered by NICE (UK) and PBAC (Australia), and agreed that on balance, it was likely reasonable to consider both IL-17 inhibitors to be clinically comparable to each other in terms of efficacy and safety.	***Ixekizumab and secukinumab for treating active non-radiographic axial spondyloarthritis: 2023***[56] In view of comparable efficacy and safety, the Committee agreed that a cost minimisation approach was appropriate to evaluate the cost-effectiveness of ixekizumab and **secukinumab**. The Committee reviewed the results of the cost-minimisation analysis, which showed that the treatment cost of **secukinumab** was lower than ixekizumab. The Committee also heard that the price of **secukinumab** in Singapore was comparable to that in overseas reference jurisdictions and considered **secukinumab** to be an acceptable use of healthcare resources.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available.

[55] https://www.ace-hta.gov.sg/docs/default-source/drug-guidances/ixekizumab-and-secukinumab-for-treating-active-non-radiographic-axial-spondyloarthritis.pdf?sfvrsn=be58c916_6

[56] https://www.ace-hta.gov.sg/docs/default-source/drug-guidances/ixekizumab-and-secukinumab-for-treating-active-non-radiographic-axial-spondyloarthritis.pdf?sfvrsn=be58c916_6

Table D-8
ClinicalTrials.Gov Completed Phase III and IV Studies Summary

Study Name	Results
Study of Efficacy and Safety of Secukinumab in Patients With Non-radiographic Axial Spondyloarthritis (PREVENT): 2022[57]	Our findings indicate that **secukinumab** 150 mg provides significant and sustained improvement in signs and symptoms of nonradiographic axial SpA through 52 weeks. Safety was consistent with previous reports., 2020[58]
Study to Demonstrate the Efficacy, Safety and Tolerability of an Intravenous Regimen of Secukinumab Compared to Placebo in Subjects With Active axSpA: 2024[59]	IV [secukinumab]was safe and effective for treatment of adults with active axSpA over 52 weeks. The safety profile of IV SEC for patients with axSpA was consistent with that of previous reports for subcutaneous SEC, and no new safety signals were observed., 2023[60]

Pediatric Psoriatic Arthritis and Enthesitis-Related Arthritis (ERA)

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.[61]

Manufacturer-Reported Benefits

Information contained in Cosentyx's FDA label, Section 14 Clinical Studies, reports on the following four studies and the resulting primary and key secondary efficacy analyses.[62] The efficacy and safety of subcutaneous Cosentyx were assessed in a two-year, 3-part, double-blind, placebo controlled, event-driven, randomized, Phase 3 study in pediatric patients (2 to less than 18 years of age) with active ERA or JPsA as diagnosed based on a modified International League of Associations for Rheumatology (ILAR) Juvenile Idiopathic Arthritis (JIA) classification criteria. The primary endpoint was time to flare: disease flare was defined as at least 30% worsening in at least three of the six JIA ACR response criteria and at least 30% improvement in not more than one of the six JIA ACR response criteria and a minimum of two active joints.

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57 https://clinicaltrials.gov/study/NCT02696031?cond=Non-radiographic%20Axial%20Spondyloarthritis%20%5C(Nr-axSpA%5C)&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=

58 https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.41477

59 https://clinicaltrials.gov/study/NCT04156620?cond=Non-radiographic%20Axial%20Spondyloarthritis%20%5C(Nr-axSpA%5C)&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=

60 https://acrabstracts.org/abstract/efficacy-and-safety-of-intravenous-secukinumab-for-the-treatment-of-active-axial-spondyloarthritis-results-from-a-randomized-double-blind-phase-3-study/

61 https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/acr.24596 It is important to note that the results of this study (INVIGORATE-1) haven't been published yet except as an abstract. Additionally, this study is for the intravenous form of Cosentyx.

62 https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

Figure D-11
JIA ACR 30, 50, 70, 90 Responses: Subcutaneous Treatment (Table 14)

Number of subjects with response (%)	JIA ACR 30	JIA ACR 50	JIA ACR 70	JIA ACR 90
JPsA (N = 34)	31 (91)	31 (91)	24 (71)	16 (47)
ERA (N = 52)	44 (85)	41 (79)	34 (65)	17 (33)

Figure D-11 shows similar responses in each JIA subtype (JPsA and ERA).

Pediatric Psoriatic Arthritis

Figure D-12
Estimated Time to Disease Flare for JPsA Patients: Subcutaneous Treatment (Figure 5)

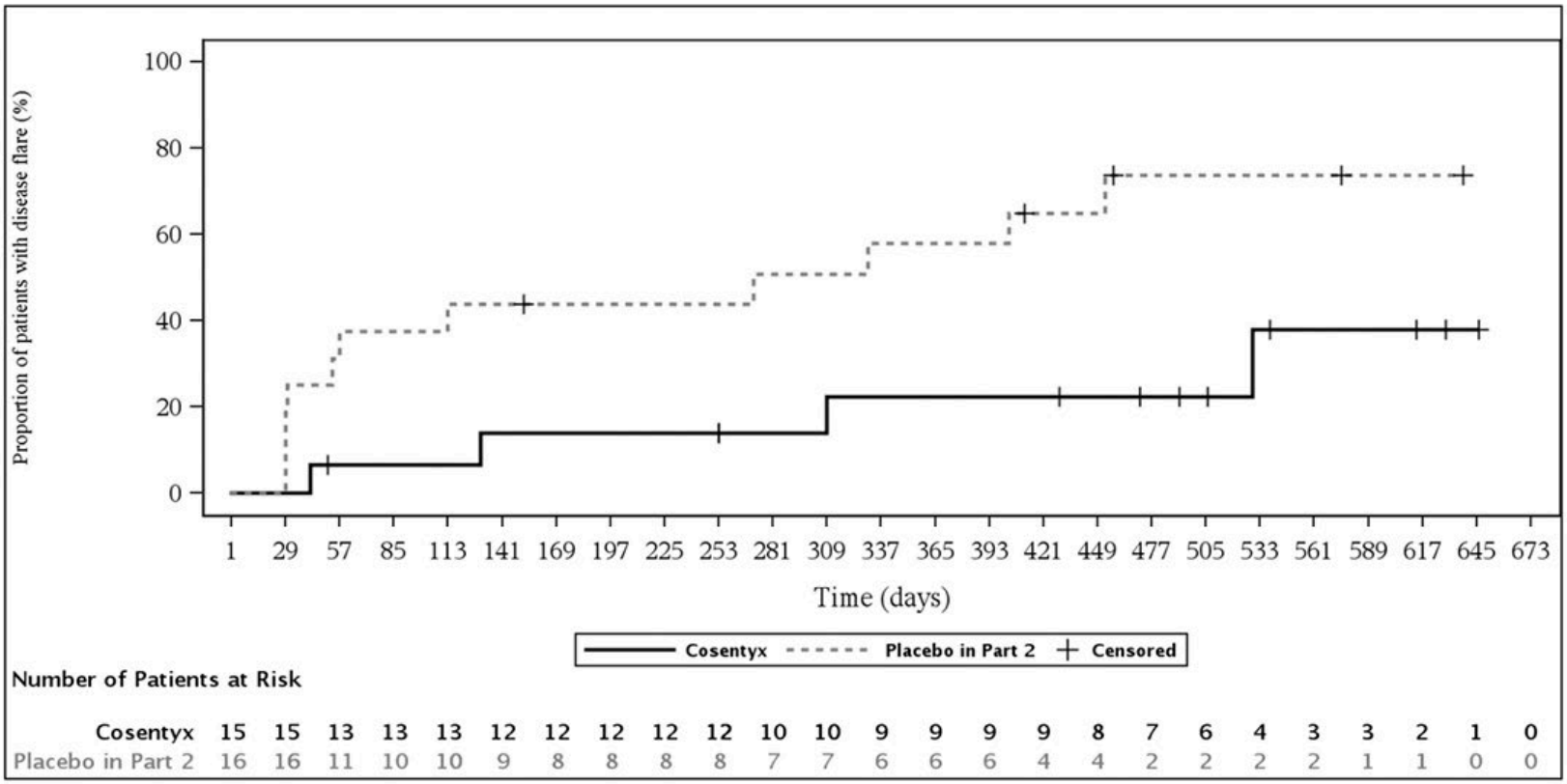


Figure D-12 shows the estimated time to disease flare for JPsA patients. The risk of flare was reduced by 85% for patients who received secukinumab compared with patients who received placebo (Hazard Ration = 0.15, 95% CI: 0.04 to 0.56).

Enthesitis-Related Arthritis

Figure D-13

Estimated Time to Disease Flare for ERA Patients (Subcutaneous Treatment)

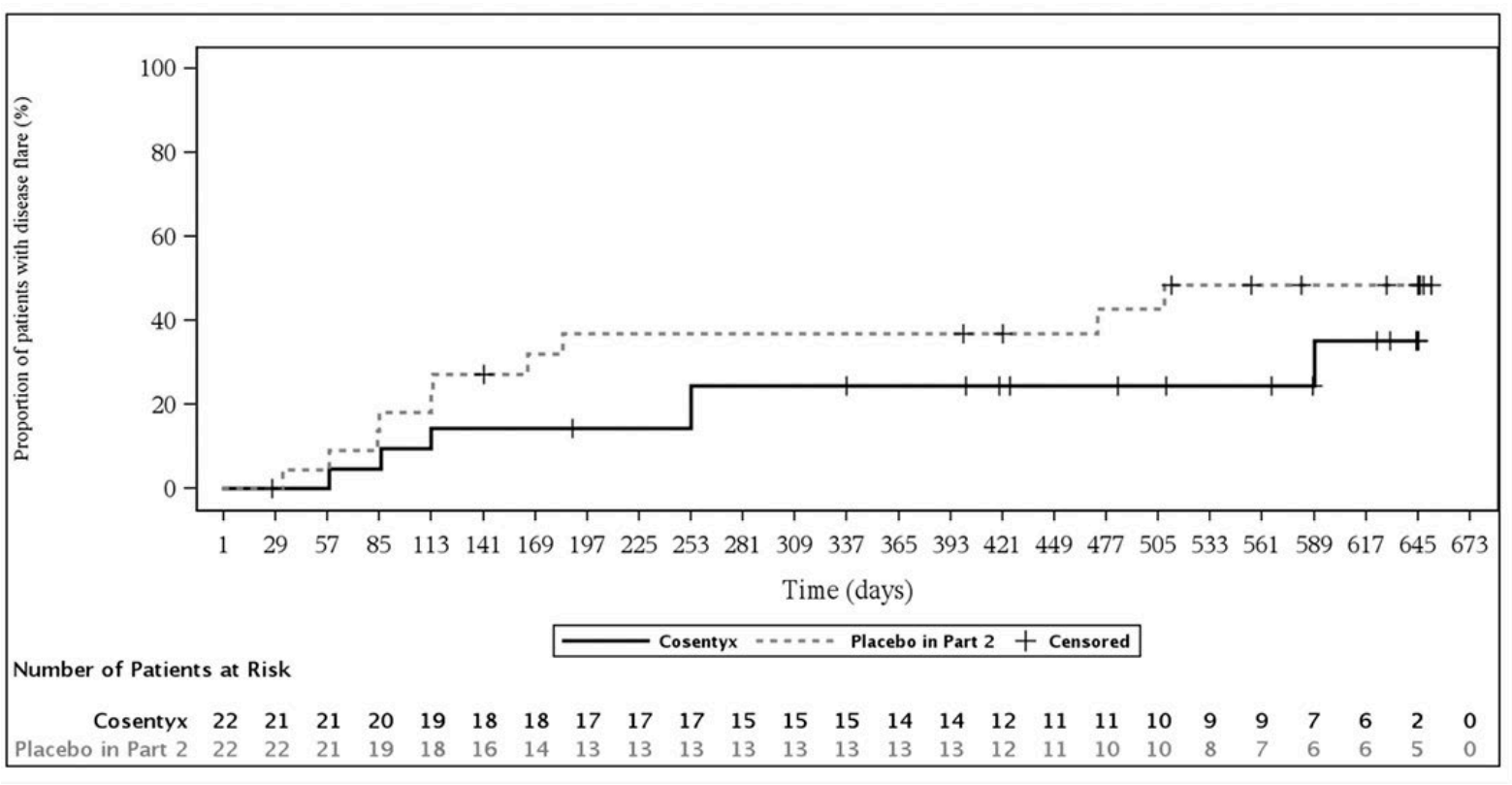


Figure D-13 shows the estimated time to disease flare for ERA patients. The risk of flare was reduced by 53% for patients who received Cosentyx compared with patients who received placebo (Hazard Ratio = 0.47, 95% CI: 0.17 to 1.32). Supplementary analyses provided confirmatory evidence of the treatment effect in ERA.

Voluntarily Submitted Manufacturer Information

Novartis voluntarily submitted the following information regarding the financial effects of Cosentyx on health, medical, or social services costs. Information included:

- "Cosentyx is also approved for active ankylosing spondylitis and active non-radiographic axial spondyloarthritis – two inflammatory arthritis conditions that affect the spine - as well as active enthesitis-related arthritis (ERA)."
- "JIA includes several disorders in children involving inflammation of the joints. Cosentyx is approved to treat two of those disorders: ERA and juvenile PsA."

Table D-9
Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
IQWiG	***Secukinumab (juvenile psoriatic arthritis) – Benefit assessment according to §35a Social Code Book V - 2022***[63] The aim of the…report is the assessment of the added benefit of **secukinumab**, alone or in combination with methotrexate, in comparison with treatment of physician's choice as the appropriate comparator therapy (ACT) in patients from 6 years of age and older with active juvenile psoriatic arthritis whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. Overall, no data are available for the assessment of **secukinumab** alone or in combination with methotrexate for the treatment of active juvenile psoriatic arthritis in patients aged 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. This resulted in no hint of an added benefit of **secukinumab** versus treatment of physician's choice; an added benefit is therefore not proven. ***Secukinumab (enthesitis-associated arthritis) – Benefit assessment according to § 35a SGB V - 2022***[64] The aim of the…report is the assessment of the added benefit of **secukinumab**, alone or in combination with methotrexate, in comparison with treatment of physician's choice as the appropriate comparator therapy (ACT) in patients from 6 years of age and older with active enthesitis-associated arthritis whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. Overall, no data are available for the assessment of **secukinumab** alone or in combination with methotrexate for the treatment of active enthesitis-associated arthritis in patients aged 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. This resulted in no hint of an added benefit of **secukinumab versus** treatment of physician's choice; an added benefit is therefore not proven.	Not applicable.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available.

[63] https://www.iqwig.de/download/a22-68_secukinumab_extract-of-dossier-assessment_v1-0.pdf
[64] https://www.iqwig.de/download/a22-69_secukinumab_extract-of-dossier-assessment_v1-0.pdf

Table D-10
ClinicalTrials.Gov Completed Phase III and IV Studies Summary

Study Name	Results
Secukinumab Safety and Efficacy in Juvenile Psoriatic Arthritis (JPsA) and Enthesitis-related Arthritis (ERA): 2022[65]	**Secukinumab** demonstrated significantly longer time to disease flare than placebo in children with ERA and JPsA with a consistent safety profile with the adult indications of psoriatic arthritis and axial spondyloarthritis.[66]

Hidradenitis Suppurativa (HS)

Relevant Medical Professional Guidelines and Manufacturer-Reported Benefits

Relevant Medical Professional Guidelines

2019 North American Clinical Management Guidelines for Hidradenitis Suppurativa: A Publication from the United States and Canadian Hidradenitis Suppurativa Foundations.[67]

Manufacturer-Reported Benefits

Information contained in Cosentyx's FDA label, Section 14 Clinical Studies, reports on the following studies and the resulting primary and key secondary efficacy analyses.[68] Two randomized, double-blind, placebo-controlled Phase 3 trials assessed the efficacy and safety of Cosentyx in the treatment of adult patients with moderate to severe hidradenitis suppurativa. The primary endpoint in both trials was the proportion of subjects who achieved a Hidradenitis Suppurativa Clinical Response (HiSCR50) defined as at least a 50% decrease in abscesses and inflammatory nodules (AN) count with no increase in the number of abscesses and/or in the number of draining fistulae relative to baseline.

[65] https://clinicaltrials.gov/study/NCT03031782?cond=Juvenile%20Idiopathic%20Arthritis&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=1
[66] https://ard.bmj.com/content/82/1/154
[67] https://www.jaad.org/article/S0190-9622(19)30368-8/fulltext
[68] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/125504s066,761349s004lbl.pdf

Figure D-14
HS Trial 1 and HS Trial 2 (Table 15)

	HS Trial 1			HS Trial 2		
	Placebo (n=180)	**COSENTYX 300 mg every 4 weeks[2] (n = 180)**	**COSENTYX 300 mg every 2 weeks[2] (n = 181)**	**Placebo (n = 183)**	**COSENTYX 300 mg every 4 weeks[2] (n = 180)**	**COSENTYX 300 mg every 2 weeks[2] (n = 180)**
HiSCR50	29.4%	41.3%	44.5%*	26.1%	42.5%*	38.3%*

[1]Multiple imputation was implemented for missing data.
[2]Subjects received COSENTYX 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3 and 4, followed by 300 mg every 4 weeks (Q4W) or every 2 weeks (Q2W).
*Statistically significant versus placebo based on the pre-defined hierarchy with overall alpha = 0.05 (two-sided).

Figure D-14 shows the results of HS Trial 1 and 2 detailing a higher proportion of subjects treated with Cosentyx achieved a HiSCR50 response than patients treated with placebo. Improvements were seen for the primary endpoint in HS subjects regardless of previous or concomitant antibiotic treatment or previous biologic exposure.

Voluntarily Submitted Manufacturer Information

Novartis voluntarily submitted the following information regarding the financial effects of Cosentyx on health, medical, or social services costs. Information included:

- "We are further developing Cosentyx in other areas of high unmet need such as Hidradenitis Suppurativa (HS), a painful and often debilitating inflammatory skin condition"

Table D-11
Hidradenitis Suppurativa Clinical and Cost Effectiveness Conclusion Summaries

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
NICE	***Secukinumab for treating moderate to severe hidradenitis suppurativa: 2023***[69] The company presented evidence from 2 identically designed, phase 3, randomised, double-blind, placebo-controlled, parallel-group trials: SUNSHINE (n=541) and SUNRISE (n=543). The committee concluded that it was plausible that **secukinumab** improved outcomes compared with placebo. Conclusion: The trials showed that secukinumab generally improved symptoms of moderate to severe HS compared with placebo.	***Secukinumab for treating moderate to severe hidradenitis suppurativa: 2023***[70] The company's base-case deterministic ICER was £10,504 per QALY gained and the EAG's was £31,073 per QALY gained. The company's probabilistic ICER was £10,411 per QALY gained and the EAG's was £31,055 per QALY gained. The committee's preferred deterministic ICER was £18,439 per QALY gained and probabilistic ICER was £18,099 per QALY gained. Because of

[69] https://www.nice.org.uk/guidance/ta935/chapter/3-Committee-discussion - QALY used in literature.
[70] https://www.nice.org.uk/guidance/ta935/chapter/3-Committee-discussion - QALY used in literature.

Source	Clinical Effectiveness Conclusion	Cost Effectiveness Conclusion
		the high level of uncertainty in the clinical and economic evidence, the committee agreed that an acceptable ICER would be around £20,000 per QALY gained. Conclusion: The most likely cost-effectiveness estimates are within what NICE considers an acceptable use of NHS resources. So, secukinumab is recommended.
IQWiG	***IQWiG: Secukinumab: 2023***[71] *The aim of [the] report is to assess the added benefit of* ***secukinumab*** *in comparison with adalimumab as the appropriate comparator therapy (ACT) in patients with active moderate to severe hidradenitis suppurativa with an inadequate response to conventional systemic therapy.* Concurring with the company, the check of the completeness of the study pool identified no RCT that would allow a direct comparison of **secukinumab** versus adalimumab. In addition, the company did not identify any study that could be considered for an indirect comparison with adalimumab via a common comparator. Since no suitable study was available that allowed an indirect comparison of **secukinumab** with the ACT in the target population. under consideration, the company did not conduct a search for suitable studies for the ACT for the indirect comparison. Since no relevant study is available for the benefit assessment, there is no hint of an added benefit of **secukinumab** in comparison with the ACT; an added benefit is therefore not proven.	Not applicable.

Emerging Evidence, Clinical Effectiveness, and Cost Effectiveness

There may be ongoing or recently completed clinical trials that the Board may want to consider. To identify more recent clinical studies typically not captured in the studies above, information is provided below for completed Phase III or IV studies found on the National Institute of Health's Clinical Trials website. The results column only contains information if there is a published, peer-reviewed study or poster available.

[71] www.iqwig.de/download/a23-51_secukinumab_extract-of-dossier-assessment_v1-0.pdf

Table D-12
ClinicalTrials.Gov Completed Phase III and IV Studies Summary

Study Name	Results
This is a Study of Efficacy and Safety of Two Secukinumab Dose Regimens in Subjects With Moderate to Severe Hidradenitis Suppurativa (HS). (SUNSHINE): 2023[72]	Method: SUNSHINE and SUNRISE were identical, multicentre, randomised, placebo-controlled, double-blind phase 3 trials done in 219 primary sites in 40 countries. Conclusion: When given every 2 weeks, **secukinumab** was clinically effective at rapidly improving signs and symptoms of hidradenitis suppurativa with a favourable safety profile and with sustained response up to 52 weeks of treatment.[73]
Study of Efficacy and Safety of Two Secukinumab Dose Regimens in Subjects With Moderate to Severe Hidradenitis Suppurativa (HS) (SUNRISE): 2023[74]	

[72] https://clinicaltrials.gov/study/NCT03713619?cond=Hidradenitis%20Suppurativa&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=1
[73] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00022-3/abstract
[74] https://clinicaltrials.gov/study/NCT03713632?cond=Hidradenitis%20Suppurativa&intr=Secukinumab&aggFilters=phase:3%204,status:com,studyType:int&rank=2

Appendix E

Cosentyx: Patient Copayment and Other Cost Sharing

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the patient copayment or other cost sharing that is associated with the prescription drug and typically required pursuant to health benefit plans issued by carriers in the state. (C.R.S. § 10-16-1406(4)(e)).

Rule: The Board will consider the copayment and other cost sharing data, across different health benefit plan designs, to the degree such information is available in the APCD, including copayment, coinsurance, deductible, and/or any other copayment and cost sharing data. (3 CCR 702-9, Part 3.1.E.2.e).

Policy: Information from ACPD data, in aggregate and by payer, for out-of-pocket costs; other data sources that approximate out-of-pocket costs not captured in APCD data; and out-of-pocket analyses will examine up to five years of data and will be consistent across all prescription drugs. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff have compiled data on patient copayment and other cost sharing for the Board's consideration in the following manner:

1. From APCD pharmacy claims, board staff pulled all claims for Cosentyx and relevant insurance coverage information for the patients on those claims from January 2018 - December 2022.
2. Using this claims data and insurance plan information, reviewed out-of-pocket amounts by deductible, copay, and coinsurance.
3. Using this claims data and insurance plan information, reviewed the out-of-pocket cost amounts by payer type (commercial, Medicare Advantage, or Medicaid) and plan type (high deductible plans or not)
4. Using information from the Colorado Division of Insurance (DOI), summarized DOI-regulated plans rate filings relevant to Cosentyx.

Data Source(s): Board staff compiled information on patient copayment and other cost sharing for the selected prescription drug from the following sources:

- APCD for patient out-of-pocket cost amounts from January 2018 - December 2022,
- Publicly available information on manufacturer assistance programs, and
- Colorado Division of Insurance (DOI) rate filing information for Colorado health benefit plans, which aggregates data including from plans and benefits and prescription drug templates.

Considerations and Data Limitations: Variation in commercial out-of-pocket costs might reflect different plan designs more than differing costs of the drug, which could impact certain patient's affordable access to the selected drug. Additionally, publicly available manufacturing assistance program information is limited.

APCD data limitations include, in regards to out-of-pocket spending, claims data includes the amount the patient was charged, it does not include how the patient paid for their portion of the drug. Data sources do not contain information on patients' use of an assistance program.

Cosentyx: Patient Copayment and Other Cost Sharing Evidence

Background

Patients typically pay for covered prescription drugs in three different ways, all of which are considered patient out-of-pocket (OOP) payment types:

- Copayment: a fixed amount paid for a covered health care service.
- Coinsurance: a percentage of costs paid for a covered health care service.
- Deductible: a total amount paid for covered health care services by a patient, after which insurance pays for the majority of remaining health care services in the remaining plan year.

Health benefit plan design can have a significant impact on both the amount a patient pays for prescription drugs and when in the plan year a patient may pay more for a prescription drug. For example, a patient's cost sharing for prescription drugs might be higher during the beginning of their plan year and then drop significantly after the patient has met their deductible amount.

Health benefit plan designs typically have the most flexibility, and therefore most variability, in the commercially insured market. While there is some variability in plan design for Medicare Advantage and Medicaid, there is very limited variability in patient copayment and cost sharing for patients covered by Medicaid. For the vast majority of patients covered by Health First Colorado (Colorado's Medicaid Program) administered by the Colorado Department of Health Care Policy and Financing, patient prescription drug copayments are between $0-$3 for each prescription drug fill and most individuals with Medicaid coverage do not have deductibles or coinsurance.[1] Since this patient out-of-pocket cost amount is very small relative to individuals with other types of insurance, it has the potential to skew the average Coloradan's out-of-pocket costs much lower than what a typical individual with commercial insurance might pay. As such, Medicaid patient out-of-pocket amounts are removed from estimates of the average out-of-pocket dollar amounts. Medicaid patient out-of-pocket amounts are included in total spend estimates, and Medicaid patients are included in utilization estimates.

Lastly, as previously mentioned, the APCD contains claims data regarding how much a patient was charged for a prescription drug; it does not include information on how the patient paid. If a patient utilized an assistance program, such as Cosentyx Connect or the Novartis Patient Assistance Foundation, that information would not be evident in the APCD. While there is no database that routinely and consistently collects information about patient assistance programs, patients, caregivers, and Cosentyx's manufacturer provided some information. See Appendices H and J for more information.

Average Patient Payments

Information regarding the average patient payment is provided below in a variety of ways to better understand the different types of patient payments (i.e., copayment vs deductible vs coinsurance) and different amounts over time. While Cosentyx has a newly approved indication that has a loading dose administered in a medical setting and is part of the medical benefit coverage, it was only approved in October of 2023, so there is no APCD utilization, and all data presented in this appendix comes from pharmacy claims.

[1] https://www.healthfirstcolorado.com/copay/

Ilumya and Siliq are identified therapeutic alternatives with very low utilization in the APCD (i.e., utilization was less than 30 patients in 2022); where appropriate, they have been removed as comparators in this appendix due to this low utilization. Skyrizi, another identified therapeutic alternative, was approved by the FDA in 2021, and only has sufficient utilization in the APCD in 2021 and 2022, so it is removed from some graphics showing changes over longer time periods and is included in others where appropriate. There has been one additional therapeutic alternative identified, Bimzelx which was approved in 2023, and therefore has no claims utilization in the APCD and is not included in this appendix.[2]

[2] See Appendix B for more information.

Figure E-1

Changes in Patient Out-of-Pocket Amounts from 2018-2022

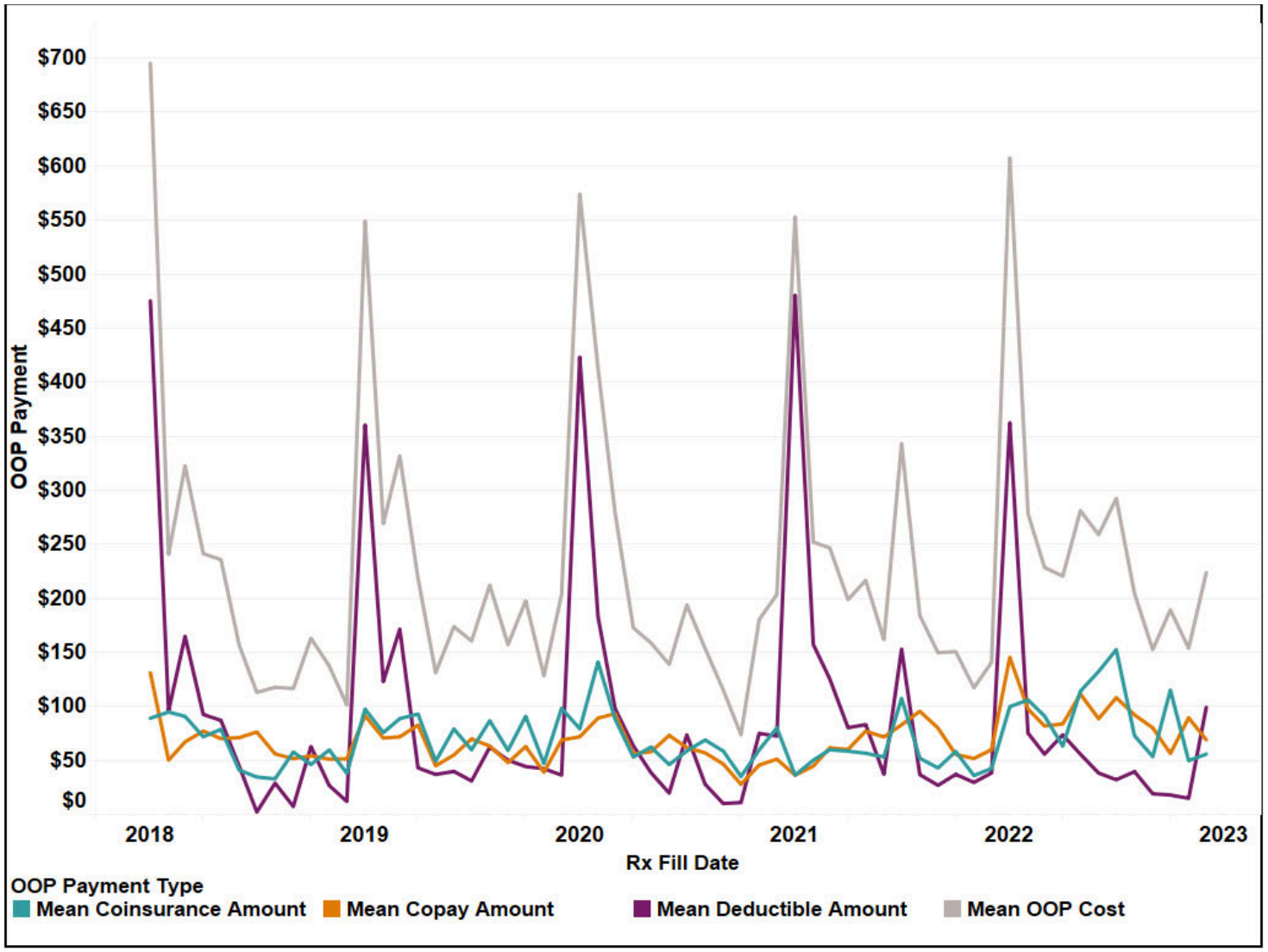


Figure E-1 shows the average out-of-pocket amount for commercially insured patients, where the orange line shows the monthly average copayment amount, the purple line shows the monthly average deductible amount, the teal line shows the monthly average coinsurance amount, and the gray line shows the monthly average total out-of-pocket amount. The deductible has a clear increase at the beginning of each plan year as patients pay more to hit their deductible.

Figure E-2

Average Commercial Out-of-Pocket Cost Comparison

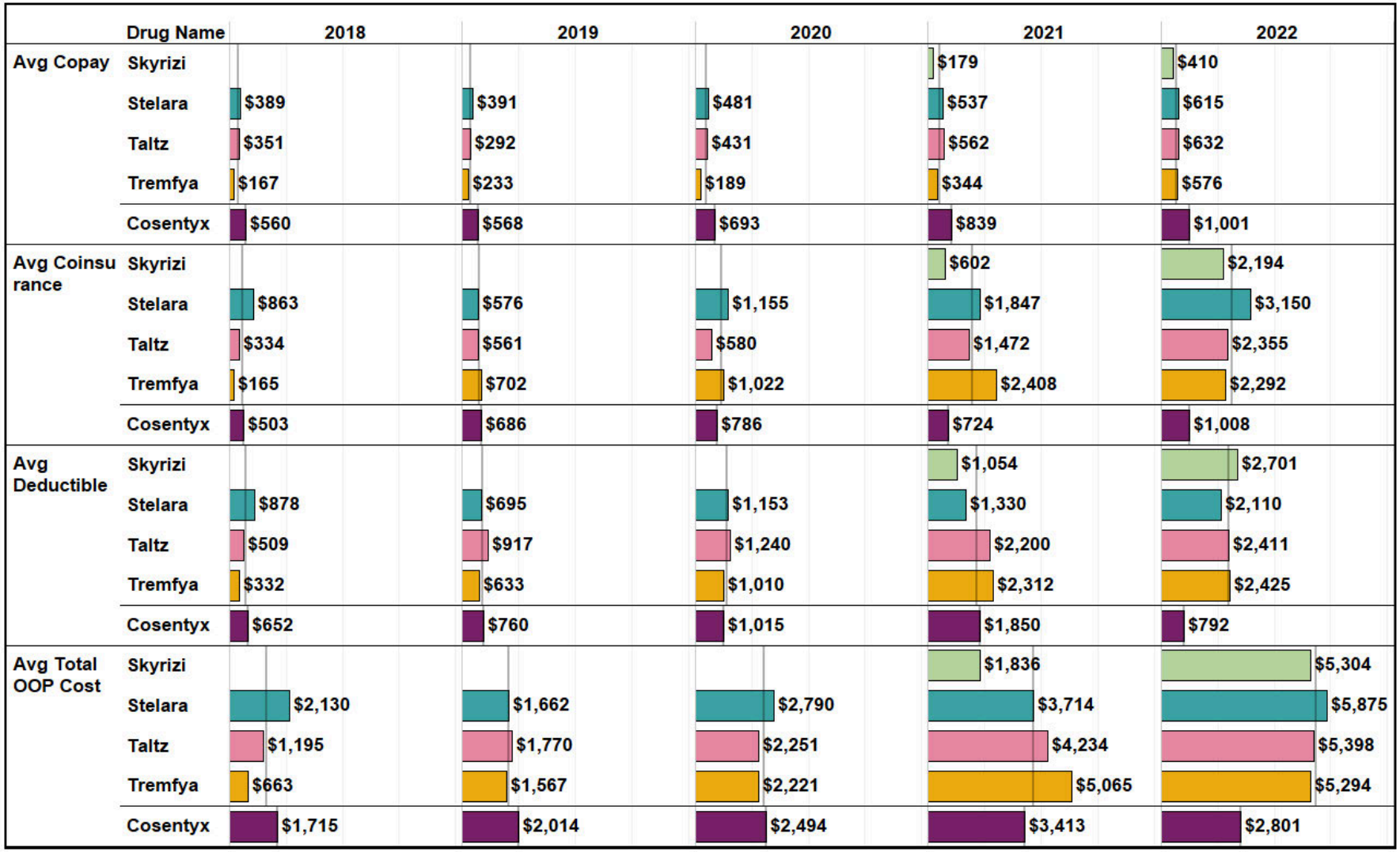


Figure E-2 shows each out-of-pocket cost type for commercially insured individuals with Cosentyx in dark purple and identified therapeutic alternatives by year. There is a light gray line that shows the average of identified therapeutic alternatives as a comparison to determine if Cosentyx is more or less expensive than the average of identified therapeutic alternatives. The 2022 total OOP cost of Cosentyx is lower than all therapeutic alternatives at $2,801 compared to the average of $5,468 of all identified therapeutic alternatives.

Table E-1

Average Annual Totals and Year-Over-Year Changes for Out-of-Pocket Amounts for Commercial Payers from 2018-2022

Drug name	Out-of-Pocket Payment Type	2018	2019	2020	2021	2022
Cosentyx	Avg Coinsurance	$503	$686	$786	$724	$1,008
	Percent Difference		*36.46%*	*14.64%*	*-7.89%*	*39.14%*
	Avg Copay	$560	$568	$693	$839	$1,001
	Percent Difference		*1.44%*	*21.87%*	*21.20%*	*19.30%*
	Avg Deductible	$652	$760	$1,015	$1,850	$792
	Percent Difference		*16.50%*	*33.60%*	*82.25%*	*-57.17%*
	Avg Total OOP Cost	**$1,715**	**$2,014**	**$2,494**	**$3,413**	**$2,801**
	Percent Difference		***17.43%***	***23.83%***	***36.88%***	***-17.94%***
Skyrizi	Avg Coinsurance				$602	$2,194
	Percent Difference					*264.10%*
	Avg Copay				$179	$410
	Percent Difference					*128.78%*
	Avg Deductible				$1,054	$2,701
	Percent Difference					*156.17%*
	Avg Total OOP Cost				**$1,836**	**$5,304**
	Percent Difference					***188.92%***
Stelara	Avg Coinsurance	$863	$576	$1,155	$1,847	$3,150
	Percent Difference		*-33.31%*	*100.64%*	*59.88%*	*70.59%*
	Avg Copay	$389	$391	$481	$537	$615
	Percent Difference		*0.64%*	*22.97%*	*11.69%*	*14.48%*
	Avg Deductible	$878	$695	$1,153	$1,330	$2,110
	Percent Difference		*-20.84%*	*65.94%*	*15.31%*	*58.64%*
	Avg Total OOP Cost	**$2,130**	**$1,662**	**$2,790**	**$3,714**	**$5,875**
	Percent Difference		***-21.97%***	***67.84%***	***33.14%***	***58.19%***

Taltz	**Avg Coinsurance**	$334	$561	$580	$1,472	$2,355
	Percent Difference		*67.93%*	*3.36%*	*153.84%*	*59.96%*
	Avg Copay	$351	$292	$431	$562	$632
	Percent Difference		*-17.00%*	*47.82%*	*30.35%*	*12.46%*
	Avg Deductible	$509	$917	$1,240	$2,200	$2,411
	Percent Difference		*80.07%*	*35.21%*	*77.40%*	*9.62%*
	Avg Total OOP Cost	**$1,195**	**$1,770**	**$2,251**	**$4,234**	**$5,398**
	Percent Difference		***48.13%***	***27.19%***	***88.08%***	***27.50%***
Tremfya	**Avg Coinsurance**	$165	$702	$1,022	$2,408	$2,292
	Percent Difference		*326.09%*	*45.70%*	*135.57%*	*-4.81%*
	Avg Copay	$167	$233	$189	$344	$576
	Percent Difference		*39.74%*	*-18.91%*	*82.15%*	*67.46%*
	Avg Deductible	$332	$633	$1,010	$2,312	$2,425
	Percent Difference		*90.54%*	*59.60%*	*129.03%*	*4.87%*
	Avg Total OOP Cost	**$663**	**$1,567**	**$2,221**	**$5,065**	**$5,294**
	Percent Difference		***136.24%***	***41.70%***	***128.05%***	***4.52%***

Table E-1 shows the average annual coinsurance, copayment, deductible, and total out-of-pocket amounts for Cosentyx and identified therapeutic alternatives, as well as the year-over-year percent change across all commercial payers from January 2018 through December 2022.

Figure E-3

Changes in Commercial OOP Amounts by Year and Drug 2018-2022

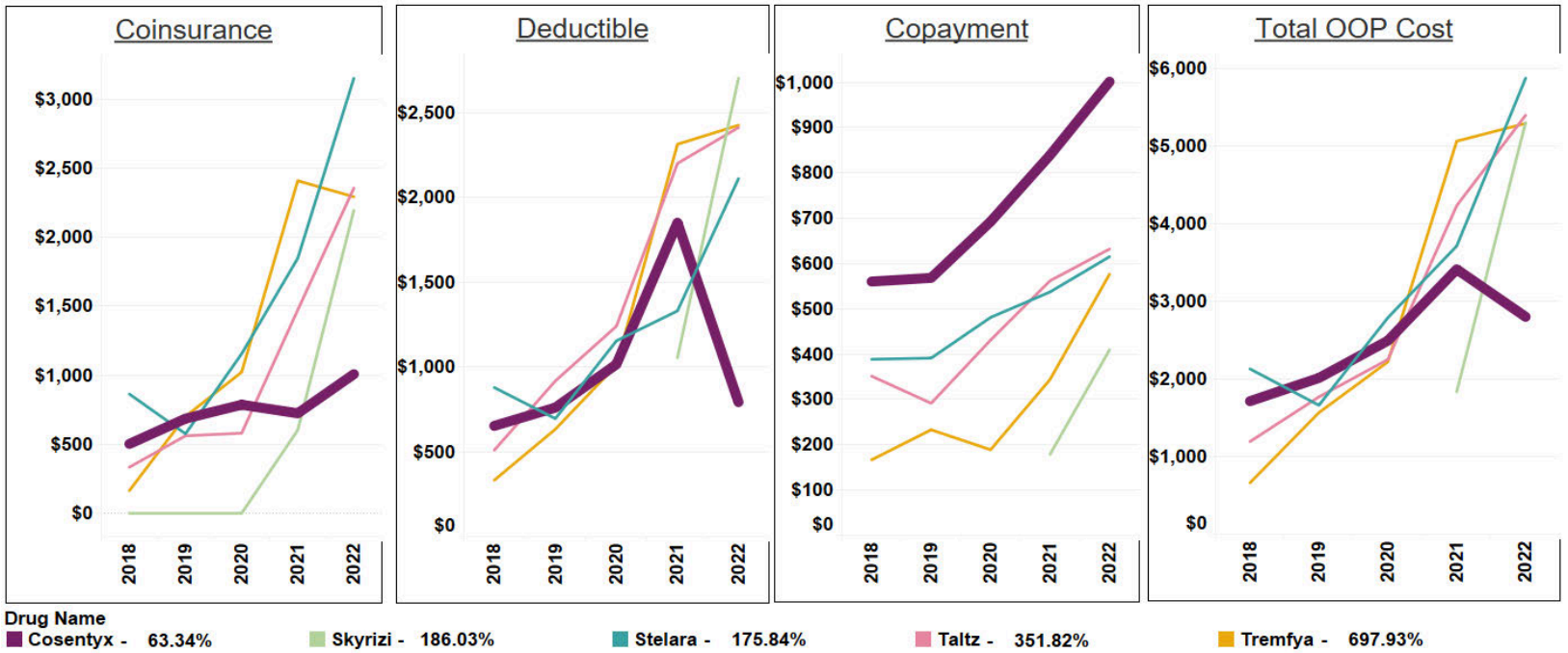


Figure E-3 shows the annual change in the annual average out-of-pocket amounts comparing Cosentyx (dark purple) to identified therapeutic alternatives. Below the graph, the percent change in total out-of-pocket cost from January 2018 - December 2022 for each drug is indicated. Cosentyx has the lowest out of pocket cost and it has increased at a lower rate than any of the identified therapeutic alternatives.

Table E-2

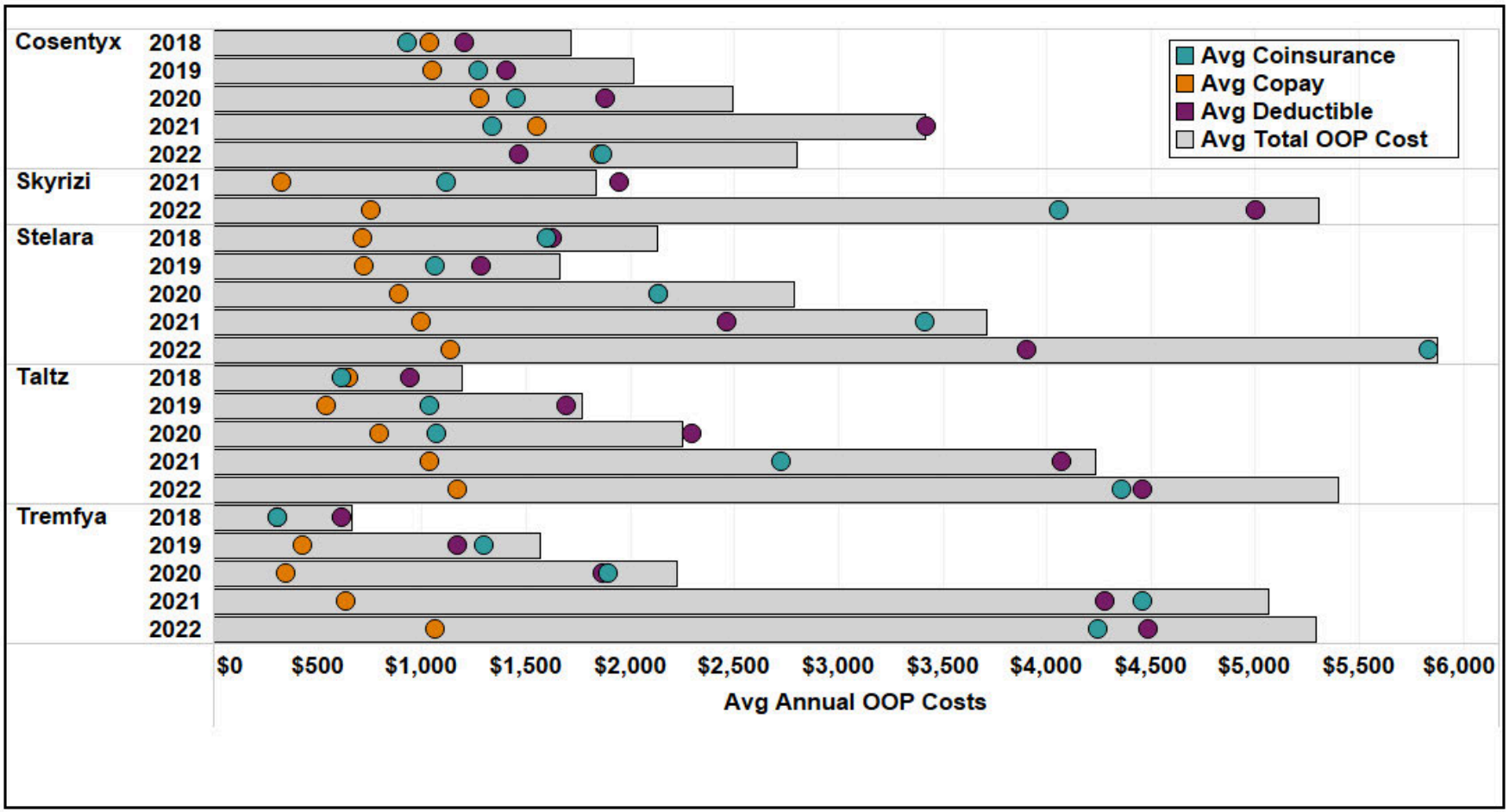
Average Monthly Commercial Out-of-Pocket Cost Information in 2022

	Cosentyx	Ilumya	Skyrizi	Stelara	Taltz	Tremfya
Average Total OOP Cost	**$257.58**	$175.46	$467.29	$489.92	$235.91	$487.70
Average Coinsurance Amount	**$92.08**	$0.00	$199.55	$272.88	$109.75	$218.11
Average Copay Amount	**$91.91**	$175.46	$37.02	$54.91	$29.26	$54.59
Average Deductible Amount	**$73.59**	$0.00	$230.73	$162.14	$96.90	$215.00
Average Days Supply	**31.3**	83.3	60.5	52.6	30.0	46.2

Table E-2 shows that in an average month in 2022, an individual with commercial insurance paid a total of $257.58 for Cosentyx, $73.59 went towards the patient's deductible, $92.08 was paid towards coinsurance, and $91.91 was paid via copayment. These payments were for an average of 31.3 days.

Figure E-4

Average Commercial Total Out-of-Pocket Cost and by Cost Sharing Type from 2018-2022



In Figure E-4, the gray bar displays the annual total out-of-pocket cost and out-of-pocket amounts are displayed as circles, with copayment in amounts in orange, coinsurance amounts as teal, and deductibles amounts as purple. This graphic shows an annual increase in total out of pocket costs for Cosentyx with large increases in 2021 driven mainly by increases in deductibles, with a decrease in total out-of-pocket costs in 2022 again driven by deductible amounts, while coinsurance and copays increased.

Figure E-5

Patient Out-of-Pocket Payment as a Percentage of Plan Payment from 2018 - 2022

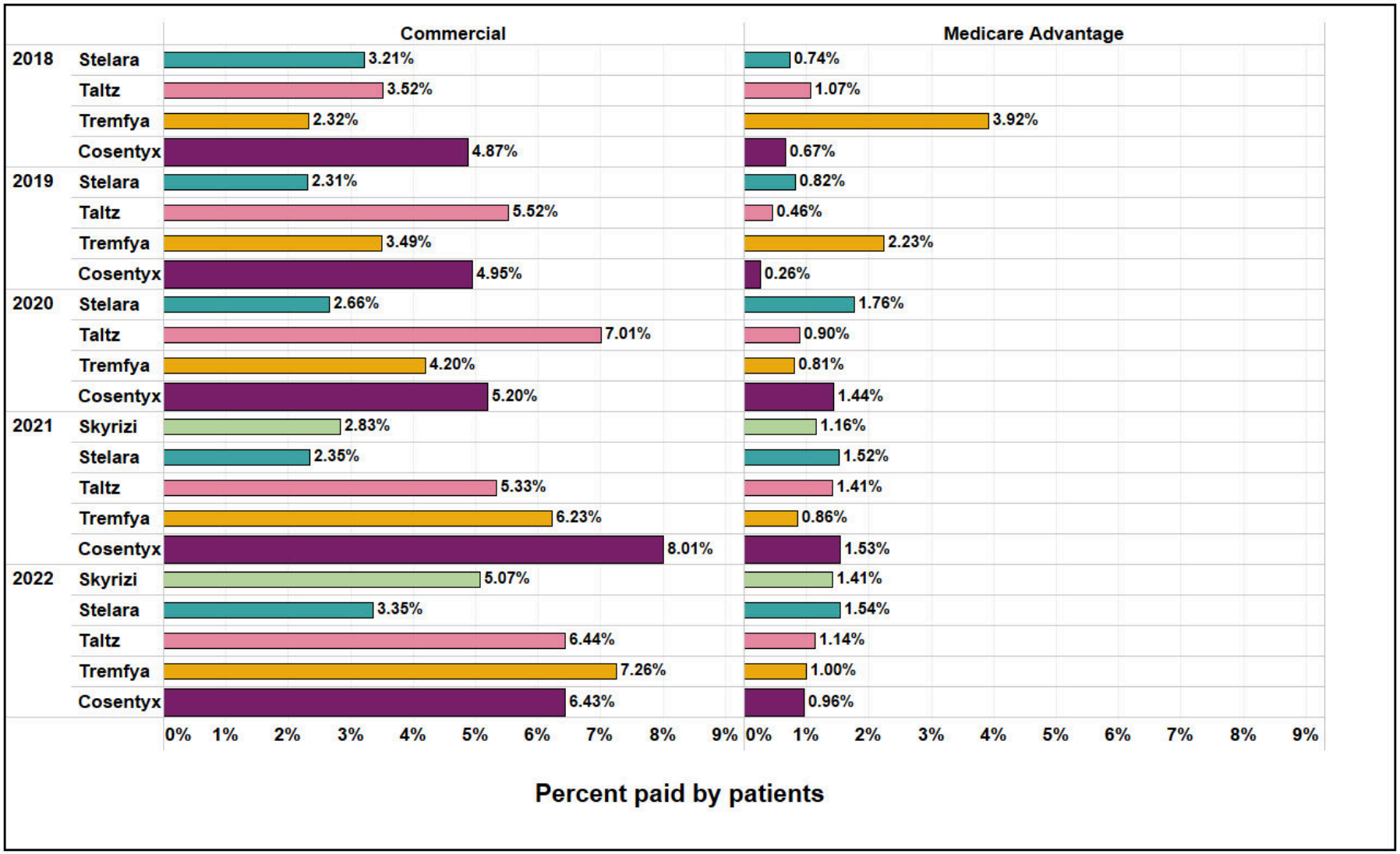


Figure E-5 provides context for what patients paid, as compared to their insurance plan, for Cosentyx or its identified therapeutic alternatives from 2018 through 2022. In 2022, commercial patients paid 6.43% of the total paid for Cosentyx, which is on par with Taltz and lower than Tremfya, but higher than Skyrizi and Stelara. Patients with Medicare Advantage coverage paid for 0.96% of the total paid amount for Cosentyx, less than all the therapeutic alternatives.

Figure E-6
Total Out-of-Pocket Cost Histogram for Cosentyx and Therapeutic Alternatives

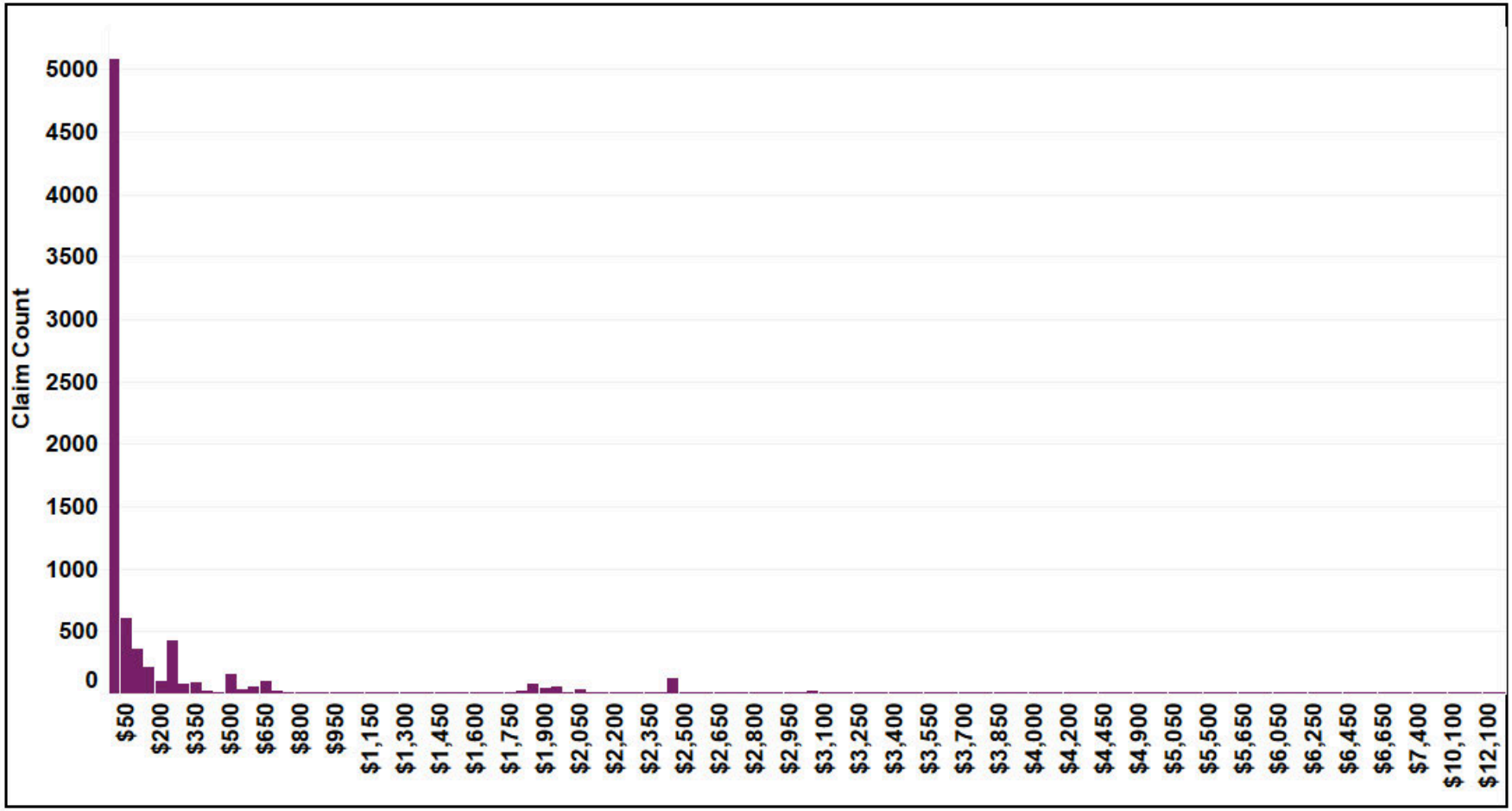


Figure E-6 shows a histogram of annual total out-of-pocket costs for individuals with commercial insurance in 2022 for utilizers of Cosentyx. It shows the variation of the total out-of-pocket costs, where 57.25% of Cosentyx utilizers paid between$0-$50, and 6.79% paid between $50 - $100 for each claim, though some individuals paid as much as $12,100 - $12,150.

Health Benefit Plan Design

A patient's insurance benefit design impacts how much of the health care service cost a patient is responsible for paying. In high deductible health plans (HDHP), a patient or family has a higher deductible that must be met before the insurance company will contribute to claims. When reviewing patient out-of-pocket costs on claims, differentiating between a high deductible benefit plan and a different benefit plan provide

some indication of why a patient's out-of-pocket cost was different at different prescription fill points throughout the benefit year. For some individuals on a high deductible plan, they may share in more of the total costs of the drug due to the higher deductible. Below is a table outlining what portion of the patients using Cosentyx on commercial health plans were enrolled in high deductible health plans. In 2021 and 2022, fewer than 6% of patients using Cosentyx were enrolled in a high deductible health plan, which means that the out-of-pocket costs presented in this report do incorporate deductibles, but are not necessarily skewed by a large portion of patients on HDHPs.

Table E-3

Percent of Patients on HDHP

Drug name	2018	2019	2020	2021	2022
Cosentyx	5.17%	5.39%	5.20%	5.03%	7.76%
Skyrizi				4.77%	5.87%
Stelara	6.00%	6.38%	5.95%	5.52%	5.79%
Taltz	6.03%	4.07%	2.98%	3.42%	5.18%
Tremfya	3.39%	1.94%	1.37%	2.33%	4.37%

Table E-3 shows the percent of patients on high deductible health plans in the APCD for Cosentyx and identified therapeutic alternatives from 2018 to 2022.

Colorado Division of Insurance Regulated Plans Rate Filing Analysis

As part of its rate review processes and enforcement of Regulation 4-2-58, the Colorado Division of Insurance (DOI) receives filings from carriers in the individual and small group markets. Rate filings are filed on an annual basis for compliance reviews by DOI. The following information was pulled by DOI staff for the affordability review and does not describe the entire market in Colorado, but can shed valuable information on benefit plan design and out-of-pocket costs.

Six of ten carriers in the Colorado market cover Cosentyx. Three carriers that cover Cosentyx require prior authorization, two carriers require prior authorization and step therapy, and one carrier covers Cosentyx with unrestricted access. In total, 289 plans provide coverage for Cosentyx. In general, the majority of carriers place Cosentyx on the middle to highest tiers, meaning a higher portion of the drug is paid by patients than drugs on lower tiers until the out-of-pocket amount under the plan is paid by the insured.

In order to summarize the cost sharing attributes of DOI-regulated plans, they are split into three parts:

- Percent coinsurance after deductible: the amount of money that a consumer pays for each claim submitted
- Copayment after deductible: the copayment associated with each visit or prescription fill once the deductible is met, and
- Copayment only.

Some of the plans that apply the copayment may apply the deductible, whereas the coinsurance plans always apply the deductible.

Table E-4
DOI-Regulated Plans Cosentyx Out-of-Pocket Costs Overview

	Total Number of Plans	Minimum	Maximum	Average	Mode
% Coinsurance after Deductible	38	0.00%	50.00%	30.30%	35.00%
Copayment after Deductible	79	$0.00	$500.00	$367.94	$350.00
Copayment	172	$0.00	$775.00	$423.63	$500.00
Total Plans	**289**				

Table E-4 shows a summary of different types of cost sharing and their applicable ranges for DOI-regulated plans covering Cosentyx. For DOI-regulated plans, the average coinsurance after deductible was 30.30%, meaning that after individuals met their plan deductible, they paid for 30.30% of the cost of Cosentyx. The data included in this summary was taken from the Master Review Tool.[3] This tool is distributed through CMS and gathers information from the plans data submitted to the Division through SERFF (the Systems for Electronic Rates and Forms Filing through the National Association of Insurance Commissioners) for the Plan Year 2024.[4]

Input from Patient and Caregivers

Table E-5
Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	3 of 5 (60%)	2 of 3 (66.6%)
$250 - $500	1 of 5 (20%)	1 of 1 (100%)
$500 - $1000	1 of 5 (20%)	1 of 1 (100%)

[3] https://www.qhpcertification.cms.gov/s/Review%20Tools

[4] The information was collected and organized through Excel to calculate the minimum, maximum, average, and mode. The minimum, maximum, average, and mode were calculated.

Appendix F

Cosentyx: Impact on Safety Net Providers

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider the impact on safety net providers if the prescription drug is available through section 340B of the federal "Public Health Service Act", Pub.L. 78-410. (C.R.S. § 10-16-1406(4)(f)).

Rule: When the prescription drug is available through section 340B of the Federal "Public Health Service Act", Pub.L. 78-410, the Board will evaluate:

- The utilization of the prescription drug by the safety net provider's patients;
- Whether the safety net provider receives a 340B discount for the prescription drug;
- Where the safety net provider does not receive a discount, whether access to the prescription drug is impeded; and
- Any other topics identified by safety net provider stakeholders for discussion. (3 CCR 702-9, Part 3.1.E.2.f).

Policy: As part of the Board's obligation to consider the impact of an affordability review of the cost of a prescription drug on safety net providers, Staff will request all safety net providers to voluntarily provide information to the Board. To facilitate gathering the information from safety net providers, Staff may request a list of 340B approved safety net providers from HCPF. (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data for the Board's consideration in the following manner:

1. Documented information provided during the stakeholder sessions to gather input from individuals with scientific or medical expertise, specifically the portion of those meetings dedicated to safety net providers. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings, as well as a survey.
2. Compiled relevant information provided by entities who submitted information voluntarily.

Data Source(s): Board staff compiled information on safety net provider impact from the following sources:

- Input from safety net providers gathered during stakeholder meetings with individuals with scientific or medical expertise, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Information provided to the Board by safety net providers may be confidential. Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all safety net providers.

Cosentyx: Impact on Safety Net Providers Evidence

Background

The 340B Drug Pricing Program is a means for certain hospitals and clinics to stretch scarce federal resources by buying outpatient prescription drugs at a discount (typically 25-50%), while receiving typical reimbursement from payers. This is intended to allow safety net providers to stretch their financial resources to reach more financially vulnerable patients and deliver comprehensive services.

Eligible health care organizations (called covered entities) are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.[1]

[1] https://www.hrsa.gov/opa

Evidence

HRSA maintains a database of covered entities and contract pharmacies, including the number of unique covered entities and addresses by covered entity type. In Colorado, there are 108 unique active covered entity names, with an associated 536 unique addresses. Additionally, there are approximately 2,974 approved and participating contract pharmacies. Table F-1 provides information on the number of unique address in Colorado designated by covered entity type:

Table F-1

340B Covered Entity Types and Number of Unique Addresses

340B Entity Type	Unique Addresses
Critical Access Hospital (CAH)	68
HRSA-Funded Health Center (CH)	212
Disproportionate Share Hospital (DSH)	160
Family Planning - Title X (FP)	38
Tribal Contract/Compact with HIS (FQHC638)	1
Health Center Program Look-Alike (FQHCLA)	1
Ryan White Part C (HV)	1
Children's Hospital (PED)	21
Rural Referral Center (RRC)	6
Comprehensive Hemophilia Treatment Center (HM)	1
Ryan White Part A (RWI)	2
Ryan White Part B (RWII)	6
Ryan White Part B ADAP Direct Purchase (RWIID)	1
Ryan White Part B ADAP Rebate Option (RWIIR)	1
Sole Community Hospital (SCH)	6
Sexually Transmitted Diseases (STD)	39
Tuberculosis (TB)	2
Urban Indian Health Center (UI)	1

Due to the differences in the form and manner in which information is submitted to HRSA and the Colorado All Payer Claims Database (APCD), Board staff did not analyze how many of these covered entities dispense Cosentyx.

In accordance with HHS 340B Drug Pricing Program Ceiling Price, prescription drug manufacturers are only allowed to charge $0.01 for a prescription drug when its 340B ceiling price calculation results in an amount less than a penny. This “penny pricing” occurs when a manufacturer raises the price of a drug substantially more quickly than the rate of inflation. While Figure 9 (also Figure A-2) does not display the rate of

inflation, the fact that Cosentyx's wholesale acquisition cost (WAC) has risen higher than inflation since its launch, suggests that Cosentyx could be, at times, subject to the 340B "penny pricing" policy.

Board staff and HCPF discussed that there was no readily available list or email listserv of 340B covered entities maintained by HCPF that could be used to facilitate Board staff outreach.

There is additional information contained in Appendix I and Appendix J which may contain additional information on impact to safety net providers not captured in this appendix. The Board may want to weigh information from all three appendices when evaluating the impact to safety net providers.

Appendix G

Cosentyx: Orphan Drug Status

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider orphan drug status. (C.R.S. § 10-16-1406(4)(g)).

Rule: The Board will identify whether the prescription drug is an orphan drug, as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414).

The Board may further consider:

- The use of the prescription drug for indications with an orphan drug designation as compared to the use of the prescription drug for other indications; and/or
- The extent to which the drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available. (3 CCR 702-9, Part 3.1.E.2.g).

Policy: The Board will compile evidence and information regarding the prescription drug's orphan drug status as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414), including:

- Reviewing the Orphan Drug List for the quarter during which the affordability review begins.
- Designation date of the prescription drug on the orphan drug list.
- Treatment designation of the prescription drug on the orphan drug list as an indicator of the population the orphan drug serves.
- Reviews of literature and patient, caregiver, and clinical expertise to understand the extent to which the prescription drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available (PDAB Policy 04, p. 7).

Underlying Methodology: Board staff compiled data regarding orphan drug status for the Board's consideration in the following manner:

- Analyzed listed indications for the selected drug, and using the FDA website, identified if any of the selected drugs treat active orphan drug indications.
- To identify if the drug meets an unmet need or treats a rare condition, Board staff reviewed information received from patient/caregiver and scientific medical training public input sessions and surveys.

Data Source(s): Board staff obtained information regarding the selected drug's orphan drug status from the following sources:

- FDA website, which contains information on current FDA labeling for each drug, FDA-approved indication, and orphan drug status,
- Results from public input sessions and surveys from patients and caregivers and individuals with scientific or medical training, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Orphan drug designations are related to the condition or indication being treated. There may be prescription drugs that treat multiple indications, but not all of those indications may be a rare disease. Data limitations that apply broadly to APCD data may apply here.

Cosentyx: Orphan Drug Status Evidence

Background

The Orphan Drug Act, passed by Congress in 1983, incentivizes the development of drugs to treat rare diseases. A rare disease is defined as a disease or condition that affects less than 200,000 people in the United States.[1] Rather, prescription drug manufacturers submit disease prevalence estimates and other documentation to the FDA in a request for orphan drug designation, which the FDA then assesses.[2]

An orphan drug is defined in the United States as one used for the treatment of a disease or condition affecting fewer than 200,000 people. The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition. Companies and other drug developers can request orphan drug designation and FDA will grant such designation if the drug meets specific criteria. While an orphan drug can be designated prior to the FDA approving the drug, it is not a guarantee that the drug will be approved for orphan drug status. Orphan drug designation provides incentives such as tax credits, fee exemptions, and a potential seven years of market exclusivity after approval.[3]

Orphan Drug Status

Cosentyx does not have any FDA-approved indications for rare diseases or active orphan drug designations.

[1] https://www.fda.gov/patients/rare-diseases-fda
[2] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-316/subpart-C/section-316.21
[3] https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products

Appendix H

Cosentyx: Input from Patients and Caregivers

Affordability Review Statute, Rule, and Policy

Statute: The Board shall consider input from patients and caregivers affected by the condition or disease that is treated by the prescription drug that is under review by the Board (C.R.S. § 10-16-1406(4)(h)(I)).

Rule: The Board will seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug by gathering information related to:

- The impact of the disease,
- Patient treatment preferences,
- Patient perspective on the benefits and disadvantages of using the prescription drug,
- Caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or
- Available patient assistance in purchasing the prescription drug.

In seeking additional information, the Board will attempt to gather a diversity of experience among patients from different socioeconomic backgrounds (3 CCR 702-9, Part 3.1.E.2.h.i).

Policy: Staff will gather input from patients and caregivers through outreach and holding a public meeting(s).

- Patients and caregivers may continue to provide input via verbal public comment and written public comment.
- During the following Board meeting(s), staff will present input provided by patients and caregivers and will report such information in their final report (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled information from patients and caregivers for the Board's consideration in the following manner:

1. Documented information provided during public input sessions to gather input from patients and caregivers being treated with Cosentyx. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings and from the survey.
2. After the survey deadline and public input sessions have concluded, Board staff aggregated responses, identified high-level themes, and presented findings to the Board in the form of a short report.

Data Source(s): Board staff compiled input from patients and caregivers for selected prescription drugs from the following sources:

- Results from public input sessions and surveys from patients and caregivers.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all patients and caregivers.

Cosentyx: Input from Patients and Caregivers Evidence

Background

Board staff gathered input from patients and caregivers in two ways: meetings and surveys. Input was gathered from patients and caregivers at one public meeting on September 21, 2023. This meeting was structured to be a focus-group style meeting to gather information on the health and financial effects of Cosentyx, and largely followed the survey questions.

In addition to input gathered through public meetings, 15 patients and caregivers completed surveys regarding the health and financial effects of Cosentyx.

At the initial time of survey release, the Board received 13 responses from patients and caregivers, two of whom are Colorado residents. At the March 18, 2024 PDAB meeting, Board members requested more information from patients and voted to reopen the surveys from April 1 to April 30, 2024. After reopening, the Board received a total of 15 responses from Cosentyx patients from across the United States, five of whom are Colorado residents.

To qualify to participate in patient and caregiver stakeholder meetings or surveys, respondents had to have been prescribed the prescription drug under review or be caregiver for an individual prescribed the drug under review. Outreach was conducted via the public listserv and website, as well as communicating with patient advocacy organizations who reached out to their patient and caregiver populations. Board staff attempted to gather a diversity of patient experiences by holding meetings in the evenings and conducting outreach to multiple consumer organizations.

Input summaries are presented below in a manner similar to how meetings and the survey were conducted: patient information, health effects of Cosentyx, and financial effects of Cosentyx. Specifically, staff collected information in a manner that encompassed the categories required by Board rule, including the impact of the disease, patient treatment preferences, patient perspective on the benefits and disadvantages of using the prescription drug, caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or available patient assistance in purchasing the prescription drug. This appendix also contains links to the two public meetings audio recordings, the survey, and survey results.

There is additional information contained in Appendix J which may contain additional input from patients and caregivers not captured in this appendix. The Board may want to weigh information from both appendices when evaluating input from patients and caregivers.

Patient Profile

The Board received a total of 15 responses from Cosentyx patients from across the United States, five of whom are Colorado residents, and one who lives outside of the United States. Two patients attended a public input session for Cosentyx, one who is currently taking Cosentyx, and one that is on a different biologic but would take Cosentyx if and when their current medication no longer works. Themes from survey responses and the public input session are summarized below.

Of the 15 total survey respondents, two were being treated for psoriasis, one was being treated for rheumatoid arthritis, six were being treated for psoriatic arthritis, one was being treated for plaque psoriasis and psoriatic arthritis, one was being treated for ankylosing spondylitis, one was being treated for axial spondyloarthritis, one was being treated for ankylosing spondyloarthritis, and two were being treated for spondyloarthritis. Of the two participants in the public session, one participant was being treated for non-radiographic axial spondylitis and the one was being treated for rheumatoid arthritis and spondylitis.

The 15 survey respondents reported being prescribed Cosentyx for the following conditions:

- Psoriatic arthritis (PsA): 6
- Psoriasis: 2
- Plaque psoriasis and PsA: 1
- Spondyloarthritis: 2
- Ankylosing spondylitis (AS): 2
- Axial spondyloarthritis: 1
- Rheumatoid arthritis: 1

Survey respondents reported being insured via:

- Individual: 2
- Employer: 9
- Medicare: 1
- Medicare & Health First Colorado: 1
- Medicare & Medicaid: 1

- Insured outside of the US: 1

Seven of 15 national respondents and two of five Colorado respondents indicated they are part of one or more priority populations as outlined in Policy.[1]

Board staff reviewed survey results and meeting recording transcripts to identify common themes about patient and caregiver experience living with their condition. Patients and caregivers stated that their condition affects their daily lives in the following ways: chronic pain, issues with mobility, flare ups, and fatigue. Majority of the participants reported that they struggle with day-to-day tasks. Several participants also stated that they struggle with depression and anxiety due to their condition.

Figure H-1
Word Cloud: Patient Experience

Figure H-1 shows a word cloud of common patient experiences heard in public meetings and surveys.

Patients and caregivers were also asked about the health outcomes that are most important to them when being treated for their condition. They indicated that pain management, increased mobility, decreasing comorbidities and fatigue, and clear skin are the most important outcomes. Overall, participants discussed the importance of quality of life for their wellbeing. One public session attendee stated an outcome that is important for them when being treated for their condition is remission.

- *"I do believe being on the right treatment could give me the possibility that maybe one day I won't have to be on these medications for the rest of my life. That's the ultimate goal."* Public input session attendee

Health Effects of Cosentyx

Patient and caregiver input regarding the health effects of Cosentyx are summarized below. More detailed information regarding each of the themes is found in meeting recordings and survey results.

[1] The Board's adopted definition of priority populations is: people experiencing homelessness; people involved with the criminal justice system; black people, indigenous people, and people of color; American Indians and Alaska natives; veterans; people who are lesbian, gay, bisexual, transgender, queer, or questioning; people of disproportionately affected sexual orientations, gender identities, or sex assigned at birth; people who have AIDS or HIV; older adults; children and families; and people with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities; and other populations as deemed appropriate by the Prescription Drug Affordability Board. 3 CCR 702-9, 1.1.C.

- *"Cosentyx dramatically reduces pain and stiffness in my spine and large joints (e.g., hips) and somewhat reduces pain and stiffness in my peripheral joints (e.g., hands)."* Survey respondent
- *"Once I got on Cosentyx the first time, which was about three years ago, within a couple of months my quality of life completely improved."* Public input session attendee
- *"I didn't get any beneficial effects when I was on Cosentyx. It did show me that what works for one person doesn't help everyone. I know several on it and they are doing great!"* Survey respondent

Common themes regarding the health effects of Cosentyx included:

- Cosentyx has reduced pain and fatigue, increased mobility, and improved overall symptoms and quality of life in the majority of patients of all indications. However, some participants indicated no improvement from taking Cosentyx.
- The most commonly reported side effects were increased susceptibility to infections and decreased immune strength. One survey respondent stated they are allergic to Cosentyx and another respondent said they got colitis after taking the drug. Seven out of 15 of the participants said they did not experience any side effects from Cosentyx.

Therapeutic Alternatives

All 15 of the survey respondents reported they have tried at least one other prescription drug to treat their condition, with 13 out of 15 reporting they cycled through another medication before being prescribed Cosentyx. Participants reported trying the following other treatments: Methotrexate, Otezla, Humira, Enbrel, Cimzia, Remicade, Simponi Aria, Ozempic, Sulfasalazine, Orencia, Xeljanz, and Taltz. Participants reported adverse effects, medication stopped working, and limited efficacy as the most common reasons for cycling through several prescriptions.

- *"Sulfasalazine, methotrexate, Otezla- they didn't work and the step therapy caused irreversible joint damage, although the Otezla was very good at clearing psoriasis plaques."* Survey respondent

Financial Effects of Cosentyx

Patients and caregivers were asked three types of questions related to the financial effects of Cosentyx. Some survey questions and meeting discussions focused on better understanding patient out-of-pocket (OOP) costs for Cosentyx, while other survey questions and meeting discussions focused on better understanding the relative financial effects of Cosentyx on health, medical, or social services costs, and a third type of question aimed to better understand patient experience with utilization management requirements. Information from all types of questions are summarized below.

Patient Costs, Patient Assistance Program, and Adherence

Patients were asked about their monthly out-of-pocket cost for Cosentyx and if the cost of the drug has ever affected their access. Nine of 15 national patients and four of five Colorado patients reported that cost has affected their access.

Table H-1
National Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	National Response	Cost Affects Access
$0 - $50	12 of 15 (80%)	6 of 12 (50%)
$250 - $500	2 of 15 (13.3%)	2 of 2 (100%)
$500 - $1000	1 of 15 (6.6%)	1 of 1 (100%)

Table H-1 shows the number of national patients who self-reported their monthly out-of-pocket costs and the number of patients within each cost bracket who reported that cost affected their access.

Table H-2
Colorado Patients' Self-Reported Out-of-Pocket Cost and Access Due to Cost

Out-of-Pocket Cost per Month	Colorado Response	Cost Affects Access
$0 - $50	3 of 5 (60%)	2 of 3 (66.6%)
$250 - $500	1 of 5 (20%)	1 of 1 (100%)
$500 - $1000	1 of 5 (20%)	1 of 1 (100%)

Table H-2 shows the number of Colorado patients who self-reported their monthly out-of-pocket costs and the number of patients within each cost bracket who reported that cost affected their access.

Table H-3
Survey Responses: Has the cost of Cosentyx ever affected your adherence to it?[2]

Survey Prompt	National Responses	Colorado Responses
I have skipped doses of the drug in order to save money.	3 of 15 (20%)	2 of 5 (40%)
I have stretched time between doses of the drug in order to save money.	3 of 15 (20%)	3 of 5 (60%)
I have changed prescription drugs to treat my condition due to cost.	6 of 15 (40%)	3 of 5 (60%)

Table H-3 shows both national and Colorado patient responses to a survey question asking if the cost of Stelara has ever affected adherence.

Assistance Programs

Patients were asked if they use copay assistance programs, discount cards, or savings provided by prescription drug manufacturers or non-profit organizations to help with out-of-pocket costs. Of 15 national respondents, 14 indicated they utilize Cosentyx Connect Program, and two still had difficulty accessing Cosentyx due to cost despite using a patient assistance program. Of five Colorado respondents, four indicated they utilize patient assistance program, and one reported difficulty affording Cosentyx despite using a patient assistance program. One public meeting attendee reported paying $0 for Cosentyx due to Cosentyx Connect.

- *"In 2024, copay assistance will no longer count toward deductible or OOP. As a result, I will not be able to afford my medication OR access other medical care, as I cannot afford any amount of copay or deductible currently."* Survey respondent

There is additional information contained in Appendix E, Appendix J, and Appendix K which may contain additional information on patient costs not captured in this appendix. The Board may want to weigh information in all four appendices when evaluating patient costs.

[2] 4 out of 15 national survey participants did not answer regarding if the cost of Cosentyx has affected their adherence to it.

Utilization Management Requirements

Table H-4
Survey response: Utilization Management

Survey Prompt	National Responses	Colorado Responses
I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	5 of 15 (33.3%)	2 of 5 (40%)
My insurance plan has dropped or switched my drug coverage after the plan year started.	3 of 15 (20%)	0 of 5 (0%)
My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.	8 of 15 (53.3%)	3 of 5 (60%)
My insurance plan requires prior approval to fill the prescription.	11 of 15 (73.3%)	4 of 5 (80%)
My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	8 of 15 (53.3%)	3 of 5 (60%)
I worry that the cost of my prescription will raise my insurance premium.	4 of 15 (26.6%)	1 of 5 (20%)

Table H-4 shows both national and Colorado patient responses to a survey question asking if they had experienced any of the listed utilization management practices.

One public meeting attendee explained that their non-adherence to Cosentyx was due to non-medical switching and prior authorization requirements rather than cost. Another public meeting attendee reported that copayment accumulators are one utilization management practice that may concern some patients.

- *"So that's an insurance glitch that really can mess with these copay programs. And it's just so scary, because patients would just have to not be on them. There's no way you could afford it."* - Public input session attendee
- *"With these diseases, continuity of care, there's nothing more important and so disrupting that for any reason just makes no sense to me at all."* - Public input session attendee

There is additional information contained in Appendix N related to utilization management requirements of Cosentyx not captured in this appendix. The Board may want to weigh information in both appendices when evaluating utilization management requirements.

Additional Financial Effects

Patients and caregivers were asked in public meetings and in surveys to share any additional information about how Cosentyx affects them financially. The most common themes from survey responses and meeting attendees were that Cosentyx reduced the amount of time and money spent on going to the doctor, hospital, or needing surgery, and has allowed them to work to support their family. Some patients reported cutting costs in other areas to pay for their medication.

- One survey respondent reported that they aren't able to take Cosentyx due to the high cost, despite being eligible for it.
- *"It would cost at least $650 a month to access this drug with my health insurance. That's more than my car payment, student loan payment, utilities, or any other monthly bill other than rent."* - Survey respondent
- *"It is unfathomable to me that an auto-immune condition like psoriasis that is proven to increase risk of other adverse health conditions has prescription drug costs this high."* Survey respondent

- *"But the fact is that when I'm stable, I don't need to go to the doctor and that's really the bottom line."* Public input session attendee

Some patients discussed difficulty with household tasks, taking sick leave for treatment, and the administrative burden required to maintain their medication:

- *"I am unable to do several household things and must hire people to do it. I have to take sick time for appointments and treatment. I'm too exhausted to take on extra work to compensate."* Survey respondent
- *"I am unable to have a paid career, which forced me to apply for and get SSDI, which is essentially government-enforced poverty for the rest of my life."* Survey respondent

There is additional information contained in Appendix D and Appendix J related to the relative financial effects of Cosentyx not captured in this appendix. The Board may want to weigh information in all three appendices when evaluating patient costs.

Audio from Public Patient and Caregiver Meetings

The audio from the September 21, 2023 public Zoom meeting is found via the following link: https://us06web.zoom.us/rec/play/i1dTqnMhNdjQ7wnLm4QSraifNk8D5MuCybjOceNEkYiWKKi_ZPyIQmmETMFWXgFD15eqF1omosebhbEj.7tN23UROMzjGul2h.

Patient and Caregiver Survey

The Patient and Caregiver Survey was live on the Prescription Drug Affordability Board website from September 12 to October 12, 2023. At the March 18, 2024 PDAB meeting, Board members requested more information from patients and voted to reopen the surveys from April 1 to April 30, 2024. Though survey results are not a representative sample of the experience of all Coloradans taking Cosentyx, the results can provide important input from patients and caregivers for the Board to consider.

Survey results are sometimes highlighted in the Summary Report and in appendices. A sample of the survey is below and full survey results are contained in the next section of this appendix. To protect patient and caregiver privacy, all names and other identifying information is redacted.

Figure H-2
Patient and Caregiver Survey (begins on next page).

Personal Information

Name *

Your answer

Email address *

Your answer

Have you attended, or do you plan to attend, a public input session for patients and caregivers? *

- ◯ Yes
- ◯ No

After you complete this survey, Board staff may have follow up questions for you. Do you consent to staff reaching out to you via email after you complete this survey?

- ◯ Yes
- ◯ No

Zip code

Your answer

If you have health insurance, what type of health insurance do you have? *

- ○ I do not have health insurance
- ○ Insured through employer
- ○ Individual (private) insurance
- ○ Medicare
- ○ Medicaid/Health First Colorado
- ○ Unsure
- ○ Other:

I am responding to this survey as: *

- ☐ A patient living with a condition which is currently or formerly being treated by Enbrel, Genvoya, Cosentyx, Stelara, or Trikafta.
- ☐ A caregiver for someone living with a condition which is currently or formerly being treated by Enbrel, Genvoya, Cosentyx, Stelara, or Trikafta.

If you are a patient, please answer this survey based on your personal experience. If you are a caregiver, please answer the survey based on the experience of the person for whom you are caring.

Which prescription drug are (you/the person you are caring for) taking currently or previously? *

Choose ▾

Health Effects

What condition does this drug treat for you?

Your answer

How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).

Your answer

What health outcomes are most important to you when being treated for your condition?

Your answer

What beneficial health effects have you experienced from using this prescription drug, if any?

Your answer

What adverse health effects have you experienced from using this prescription drug, if any?

Your answer

What factors led you to the prescription drug you are currently taking? Select all that apply:

- [ ] It's the only one designated for my condition.
- [ ] I cycled through other medications that didn't work before finding this one.
- [ ] It's the drug my provider prescribed and it works for me.
- [ ] It was required by my insurance company.
- [ ] The method of delivery or injection works best for me.
- [ ] Other:

Have you tried taking other prescription drugs to treat your condition? If so, how many?

- ○ None
- ○ Yes, one other treatment.
- ○ Yes, two other treatments.
- ○ Yes, three other treatments.
- ○ Yes, more than three other treatments.
- ○ Unsure

If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?

Your answer

Financial Effects

How much do you pay out-of-pocket each month for the prescription drug? By out-of-pocket, we mean after insurance or any patient assistance program used to cover the cost of the medication.

- ○ $0-$50 per month
- ○ $50 - $100 per month
- ○ $100 - $150 per month
- ○ $150 - $250 per month
- ○ $250 - $500 per month
- ○ $500- $1000 per month
- ○ More than $1000 per month

Has the cost of this drug ever made it difficult for you to access it?

- ○ Yes
- ○ No

Has the cost of this drug ever affected your adherence to it? Select all that apply.

- ☐ I have skipped doses of the drug in order to save money.
- ☐ I have reduced the dose of the drug in order to save money.
- ☐ I have stretched time between doses of the drug in order to save money.
- ☐ I have changed prescription drugs to treat my condition due to cost.
- ☐ Other:

How does this drug impact you and/or your family? Select all statements that are true for you.

- [ ] This medication reduces the amount of time and money spent going to the doctor.
- [ ] This medication reduces the amount of time and money spent going to the hospital or needing surgery.
- [ ] This medication allows me to work and help support my family.
- [ ] Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.
- [ ] Out-of-pocket costs have caused me to accrue medical debt.

The following questions are centered around any financial assistance you may have received to help purchase the prescription drug. Many patients requiring ongoing treatments for chronic diseases receive financial assistance from drug manufacturers and non-profit organizations in the form of copay assistance programs, discount cards, or savings cards. These help patients pay their out-of-pocket costs (such as deductibles, copays, etc.) for their prescription drugs.

Do you/the person you are caring for use, or have ever used, any copay assistance programs, discount cards, or savings that are provided by prescription drug manufacturers, or non-profit organizations to help with out-of-pocket costs (such as deductibles, copays, etc.) for this drug?

- ◯ Yes
- ◯ No

If you replied "yes" to the question above, how did you hear about the financial assistance?

- ○ Friend or family member
- ○ My provider
- ○ My pharmacist
- ○ My insurance company
- ○ Prescription drug manufacturer
- ○ Internet search
- ○ Other:

Do you have difficulty affording the drug despite using a patient assistance program?

- ○ Yes
- ○ No

If you are insured, please select any of the following statements that are true for you. Select all that apply.

- ☐ I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.
- ☐ My insurance plan has dropped or switched my drug coverage after the plan year started.
- ☐ My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor.
- ☐ My insurance plan requires prior approval to fill the prescription.
- ☐ My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.
- ☐ I worry that the cost of my prescription will raise my insurance premium.

Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?

Your answer

Patient and Caregiver Survey Results

Survey results are provided first for Personal Information, then Health Effects, followed by Financial Effects.

Table H-1

Patient and Caregiver Survey Results

Personal Information and Health Effects

ID #	Patient /Caregiver?	Drug?	CO Resident	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
1	Patient	Cosentyx	Yes	80210	Individual (private) insurance		Psoriasis	I have psoriasis that can be found on different parts of my body. It has resulted in food intolerances with poor gut health and prediabetes.	I care most about reducing the plaques and decreasing my risk of comorbidities.	
2	Patient	Cosentyx	Yes	80222	Insured through employer	People with disabilities	spondyloarthritis	Constant flares until I can figure out a medication. Pain, anxiety, and limited mobility in sitting/standing long periods of time,	Quality of life- lower pain and higher mobility. Less fatigue	Allergic to cosentyx
3	Patient	Cosentyx	No		Insurance at my country		S/A	Chronic pain, fatigue, anxiety/ depression, low mobility, no work, no activity no at all.	Relief of pain	None
4	Patient	Cosentyx	No	48917	Insured through employer	Children and families	Psoriatic arthritis	Pain mobility and anxiety issues	Less pain. discomfort. Joint damage.	Less pain and swelling of joints

ID #	Patient /Caregiver?	Drug?	CO Resident	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
5	Patient	Cosentyx	No	95838	Medicare and Medicaid	People who are lesbian, gay, bisexual, transgender, queer, or questioning, People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth, People with disabilities	Axial spondyloarthritis	I rely on SSDI due to the pain, fatigue and limited mobility caused by spondyloarthritis. All my joints are impacted. I am unable to cook and clean, and I often must rest in the middle of changing sheets. I sometimes must choose between showering or eating because of energy limitations. I sometimes spend weeks in bed due to pain between 8-9 on the 1-10 pain scale. I also experience comorbid depression and anxiety.	Pain at a 5 on the 1-10 pain scale would feel like heaven and allow me to function better. Sleep improvement is also important, as well as decreased fatigue all these would support my ability to care for basic needs and also engage in activities that are enjoyable, like gardening or hosting potlucks with friends.	My self-reported symptoms have improved. On the occasions I've had to pause injections due to infections or vaccines, I feel a notable increase in sacroiliac pain, which worsens my fatigue and sleep. So, Cosentyx helps reduce pain, increase mobility and energy, and aids with sleep.

ID #	Patient /Caregiver?	Drug?	CO Resident	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
6	Patient	Cosentyx	No	63376	Insured through employer		Psoriatic Arthritis	Daily impact varies from a sore wrist to not being able to cut food, open a water bottle, type for work. I have also quit recreational exercise like soccer due to increased injury and pain. During a flare it is hard to sleep, especially on my side due the pain in my shoulders and hips.	Reduced pain during daily activities. Less fatigue. Little to no flares.	Little to no fatigue. Less pain. Less flares. Ability to play soccer, run and other exercise.
7	Patient	Cosentyx	No	3820	Insured through employer		Psoriatic arthritis	Mobility, adls, employment	Mobility, stopping joint destruction	Improved disease remission
8	Patient	Cosentyx	No	98625	Insured through employer		Medically induced psoriasis	Had no affect other than my nervousness to inject myself.	Clear skin	No change for me unfortunately
9	Patient	Cosentyx	No	45439	Insured through employer		Psoriatic Arthritis	Chronic pain; discomfort, fatigue, limited exercise and mobility at work	Mobility, pain relief	Minimal joint pain- treated and tolerable, more mobility, ability to exercise regularly

ID #	Patient /Caregiver?	Drug?	CO Resident	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
10	Patient	Cosentyx	Yes	80211	Individual (private) insurance		ankylosing spondylitis	Severe inflammatory pain in spine and joints without medication, exacerbated by sitting and standing; falling; permanent fusion of bones/cartilage that has turned to bone (including rib fusion that restricts breathing); limits work, housework, ability to use hands to dress and feed myself	Preservation of function, pain management	Cosentyx dramatically reduces pain and stiffness in my spine and large joints (e.g., hips) and somewhat reduces pain and stiffness in my peripheral joints (e.g., hands)
11	Patient	Cosentyx	No	60506 but was 61032 when on Cosentyx	Medicaid/ Health First Colorado	People with disabilities	Psoriatic Arthritis	Joint and tendon pain fatigue immobility	Energy mobility, pain relief	Energy mobility

ID #	Patient /Caregiver?	Drug?	CO Resident	Zip	Insurance type	Priority Population	Condition	How does the condition affect your daily life, or the life of person you are caring for? (Consider mobility, self care, usual activities like work, study, housework, family, leisure activities, pain/discomfort, any anxiety/depression).	What health outcomes are most important to you when being treated for your condition?	What beneficial health effects have you experienced from using this prescription drug, if any?
12	Patient	Cosentyx	No	32712	Insured through employer	People with disabilities	Rheumatoid Arthritis	Taking care of the house can be difficult. Anxiety and Depression can be made much worse especially during a flare.	Less pain, I want to be able to experience life.	I didn't get any beneficial effects when I was on Cosentyx. It did show me that what works for one person, doesn't help everyone. I know several on it and they are doing great!
13	Patient	Cosentyx	No	19026	Insured through employer	People with disabilities	Ankylosing Spondlyoarthritis	Difficulty with daily living skills, walking, working, traveling, house chores, depression)	Improved mobility, decreased pain, decreased fatigue	Improved mobility, decreased pain
14	Patient	Cosentyx	Yes	80224	Insured through employer		Plaque Psoriasis and Psoriatic Arthritis	Impacts quality of life with pain on hands and joint pain	clear skin, ease of arthritic symptoms in joints	Joint pain is better and psoriatic arthritis is halted from progressing
15	Patient	Cosentyx	Yes	80537	Medicare	Older adults, People with disabilities	Psoriatic Arthritis	Pain, limited mobility	pain relief	reduced symptoms

Health Effects cont.

ID #	What adverse health effects have you experienced from using this prescription drug, if any?	What factors led you to the prescription drug you are currently taking? Select all that apply:	Have you tried taking other prescription drugs to treat your condition? If so, how many?	If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?
1		The cost of cosentyx has resulted in me not being able to access this drug.	Yes, two other treatments.	Otezla and Methotrexate.
2	Allergic to cosentyx. Extreme weight loss	I cycled through other medications that didn't work before finding this one., This medication did not work for me	Yes, more than three other treatments.	Humira, methotrexate, rinvoq, influximab
3	Colitis	I cycled through other medications that didn't work before finding this one.	Yes, two other treatments.	I do use Humira, now I'm on Xeljens and it's failing to treat me too.
4	None known	I cycled through other medications that didn't work before finding this one.	Yes, three other treatments.	Sulfasalazine methotrexate otezla- they didn't work and the step therapy caused irreversible joint damage. although the otezla was very good at clearing psoriasis plaques
5	I am more susceptible to infections.	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Enbrel, Cimzia, Remicade. Corticosteroids (current), DMARDs, opioid medications (current). Occasional rounds of corticosteroids trigger oral thrush but they enhance the good impacts of Cosentyx and give me weeks of a positive baseline of functioning. Opioids (norco) are necessary for me to sleep without agonizing pain.
6	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Humira, Enbrel, Stelara, Cimzia, Tremfya, Skyrizi, Methotrexate, Sulfasalazine, Celebrex
7		I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Humira (drug induced lupus), stelae's, cosentyx

ID #	What adverse health effects have you experienced from using this prescription drug, if any?	What factors led you to the prescription drug you are currently taking? Select all that apply:	Have you tried taking other prescription drugs to treat your condition? If so, how many?	If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?
8	None	It was what my prescriber hoped would work for my psoriasis.	Yes, one other treatment.	Otezla, very effective and mostly cleared my skin.
9	None	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me., The method of delivery or injection works best for me.	Yes, two other treatments.	Methotrexate- chronic nausea; vomiting, dizziness, diarrhea Diclofenic sodium- no effects
10	None	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Embrel (adverse effects), Humira (stopped working), Taltz (adverse effects), Remicade (ineffective), Simponi (severe adverse reaction), multiple types of antiinflammatory medications (multiple adverse reactions, one removed from market), multiple types of steroids (adverse effects/limited efficacy)
11	I think it triggered seasonal allergies	I cycled through other medications that didn't work before finding this one., The method of delivery or injection works best for me.	Yes, more than three other treatments.	Embrel, humira, ozempic, prednisone methotrexate remicade
12	Since it didn't have any benefits for me, I suffered a lot more pain during those six months	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira, Enbrel, Remicade, Xeljanz, Rinvoq, Orencia, Simponi Aria. They worked for anywhere beteen 6 months and a year and a half. I'm currently on Simponi Aria
13	None	I cycled through other medications that didn't work before finding this one.	Yes, more than three other treatments.	Humira (shingles), Actemra (Anaphylaxis), Orencia, Kevzara, Remicade

ID #	What adverse health effects have you experienced from using this prescription drug, if any?	What factors led you to the prescription drug you are currently taking? Select all that apply:	Have you tried taking other prescription drugs to treat your condition? If so, how many?	If you have tried other prescription drugs to treat your condition, what were they? Were there any beneficial or adverse health effects of these other prescription drugs?
14	respiratory infections, lack of immune system	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	Otezla and Taltz. Otezla had severe gastro symptoms and stopped working, Talz had minimal side effects besides making me immunocompromised.
15	none	I cycled through other medications that didn't work before finding this one., It's the drug my provider prescribed and it works for me.	Yes, three other treatments.	humira, enbrel, I can't recall the others

Financial Effects

ID #	How much do you pay out-of-pocket each month for the prescription drug? By out-of-pocket, we mean after insurance or any patient assistance program used to cover the cost of the medication.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	Do you/the person you are caring for use, or have ever used, any copay assistance programs, discount cards, or savings that are provided by prescription drug manufacturers, or non-profit organizations to help with out-of-pocket costs (such as deductibles, copays, etc.) for this drug?
1	$500- $1000 per month	Yes	I have changed prescription drugs to treat my condition due to cost.		No

ID #	How much do you pay out-of-pocket each month for the prescription drug? By out-of-pocket, we mean after insurance or any patient assistance program used to cover the cost of the medication.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	Do you/the person you are caring for use, or have ever used, any copay assistance programs, discount cards, or savings that are provided by prescription drug manufacturers, or non-profit organizations to help with out-of-pocket costs (such as deductibles, copays, etc.) for this drug?
2	$250 - $500 per month	Yes	I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes
3	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money.	Out-of-pocket costs have caused me to accrue medical debt.	Yes
4	$0-$50 per month	No	The PBM has delayed me getting my dose to save itself money and this was worsened my health	This medication allows me to work and help support my family.	Yes
5	$0-$50 per month	No	N/a	This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery.	Yes

ID #	How much do you pay out-of-pocket each month for the prescription drug? By out-of-pocket, we mean after insurance or any patient assistance program used to cover the cost of the medication.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	Do you/the person you are caring for use, or have ever used, any copay assistance programs, discount cards, or savings that are provided by prescription drug manufacturers, or non-profit organizations to help with out-of-pocket costs (such as deductibles, copays, etc.) for this drug?
6	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes
7	$0-$50 per month	Yes		This medication reduces the amount of time and money spent going to the doctor., This medication reduces the amount of time and money spent going to the hospital or needing surgery., This medication allows me to work and help support my family.	Yes
8	$0-$50 per month	No	No	This medication reduces the amount of time and money spent going to the doctor.	Yes
9	$0-$50 per month	No		This medication reduces the amount of time and money spent going to the doctor., This medication allows me to work and help support my family.	Yes
10	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money.	This medication allows me to work and help support my family.	Yes

ID #	How much do you pay out-of-pocket each month for the prescription drug? By out-of-pocket, we mean after insurance or any patient assistance program used to cover the cost of the medication.	Has the cost of this drug ever made it difficult for you to access it?	Has the cost of this drug ever affected your adherence to it? Select all that apply.	How does this drug impact you and/or your family? Select all statements that are true for you.	Do you/the person you are caring for use, or have ever used, any copay assistance programs, discount cards, or savings that are provided by prescription drug manufacturers, or non-profit organizations to help with out-of-pocket costs (such as deductibles, copays, etc.) for this drug?
11	$0-$50 per month	Yes	I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes
12	$0-$50 per month	No		Out-of-pocket costs have caused me to accrue medical debt.	Yes
13	$250 - $500 per month	Yes	I have changed prescription drugs to treat my condition due to cost., My insurance rejected my doctor's recommendation due to cost	This medication allows me to work and help support my family., Due to the cost of this medication, I have had to cut costs in other areas of my life (e.g. housing, groceries, vacations, etc.) to pay for the medication.	Yes
14	$0-$50 per month	No			Yes
15	$0-$50 per month	Yes	I have skipped doses of the drug in order to save money., I have stretched time between doses of the drug in order to save money., I have changed prescription drugs to treat my condition due to cost.	This medication reduces the amount of time and money spent going to the doctor.	Yes

Financial Effects cont.

ID #	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
1			My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	I have not been able to use this prescription drug because the cost is so high for me. It would cost at least $650 a month to access this drug with my health insurance. That's more than my car payment, student loan payment, utilities, or any other monthly bill other than rent. It is unfathomable to me that an auto-immune condition like Psoriasis that is proven to increase risk of other adverse health conditions has prescription drug costs this high. Please do an affordability review of Cosentyx so patients like me can actually access this drug and not be prevented because of the absurd high cost.
2	Friend or family member	Yes	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Absence from work
3	My provider	Yes	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	Sometimes the program doesn’t provide me the drug, so I fall in a flare that can cost every effort to take me out of so pain.

ID #	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
4	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	Dealing with the insurance company and PBM takes time away from my work, creating financial costs to my family.
5	Mutual aid information from fellow patients online.	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I am unable to have a paid career, which forced me to apply for and get SSDI, which is essentially government-enforced poverty for the rest of my life
6	My provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance plan requires prior approval to fill the prescription.	
7	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	

ID #	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
8	My provider	No	My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	No
9	Prescription drug manufacturer	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get., I worry that the cost of my prescription will raise my insurance premium.	No
10	My provider	No	My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	I have a high-deductible plan through the marketplace. I cannot afford the deductible. Currently the Cosentyx copay assistance program covers 100% of my deductible and out-of-pocket. In 2024, copay assistance will no longer count toward deductible/OOP. As a result, I will not be able to afford my medication OR access other medical care, as I cannot afford any amount of copay or deductible currently. I have a separate life-threatening condition that requires IV infusions every two weeks and other expensive medications, which I will not be able to access due to this change. I am self-employed and the sole source of income in my household (my husband has cancer). Insurers should be required to continue counting copay assistance contributions toward deductibles/OOP limits as they do now (and will be required again in 2025 per Colorado law).

ID #	If you replied "yes" to the question above, how did you hear about the financial assistance?	Do you have difficulty affording the drug despite using a patient assistance program?	If you are insured, please select any of the following statements that are true for you. Select all that apply.	Do you (as patient or caregiver) experience any other financial impacts of the condition and prescription drug (e.g. transportation costs, absence from work, etc.)?
11	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., My insurance plan requires prior approval to fill the prescription.	No
12	Prescription drug manufacturer	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	I have had to miss work because of the drugs not being right for me.
13	and provider	No	My insurance plan has dropped or switched my drug coverage after the plan year started., My insurance required me to try a medication that I had previously failed, or required me to use a drug that was not recommended by my doctor., I worry that the cost of my prescription will raise my insurance premium.	I am unable to do several household things and must hire people do to it. I have to take sick time for appointments and treatment. I'm too exhausted to take on extra work to compensate.
14	My insurance company	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance., My insurance plan requires prior approval to fill the prescription., My insurance plan limits my supply of the drug (e.g. only offers a 30 day supply with no 90 day supply option) or number of refills I am able to get.	
15	My provider	No	I have chosen to not use my insurance because a patient financial assistance program makes the drug more affordable than my insurance.	

Appendix I

Cosentyx: Input from Individuals with Scientific or Medical Training

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board. (C.R.S. § 10-16-1406(4)(h)(II)).

Rule: Individuals with Scientific or Medical Training: The Board will seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board, including:

- The impact of the disease,
- Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or
- Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage. (3 CCR 702-9, Part 3.1.E.2.h.ii).

Off-label usage means the use of a prescription drug for a disease or medical condition that is outside the FDA-approved indication(s) (3 CCR 702-9, 1.1.C).

Policy: Staff will gather input from individuals who possess scientific or medical training through outreach and holding a public meeting(s).

- Individuals who possess scientific or medical training with respect to the condition or disease may continue to provide input via verbal public comment and written public comment.
- During the following Board meeting(s), Staff will present input provided by individuals with scientific or medical training and will report such information in their final report. (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled data for Cosentyx for the Board's consideration in the following manner:

1. Documented information provided during the stakeholder sessions to gather input from individuals with scientific and medical training specific to Cosentyx. Staff attempted to compile information directly related to the information outlined in rule during stakeholder meetings and from the survey.
2. After the survey deadline and public input sessions have concluded, Board staff aggregated responses, identified high-level themes, and presented findings to the Board in the form of a short report.

Data Source(s): Board staff compiled information from individuals with scientific or medical training for selected prescription drugs from the following sources:

- Results from public input sessions and surveys from individuals with scientific or medical training.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all individuals with scientific and medical expertise.

Cosentyx: Input from Individuals with Scientific or Medical Training Evidence

Background

Board staff gathered input from individuals with scientific or medical training in two ways: meetings and surveys. Input was gathered from one individual at a public meeting on September 21, 2023. In addition to input gathered through the public meeting, three individuals completed surveys regarding the health and financial effects of Cosentyx. One respondent both attended the public meeting and completed the survey. Additional input was gathered from three individuals with scientific or medical training via one additional small group meeting.[1]

To qualify to participate in meetings or surveys, respondents had to have scientific or medical experience with Cosentyx. Outreach was conducted via the public listserv and website.

Input summaries are presented below in a manner similar to how meetings and the survey were conducted: health effects of Cosentyx and financial effects of Cosentyx. Specifically, staff collected information in a manner that encompassed the categories required by Board rule, including the impact of the disease, perspective on the benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage. This appendix also contains links to the public meeting audio recording, the survey, and survey results.

There is additional information contained in Appendix J which may contain additional input from individuals with scientific or medical training not captured in this appendix. The Board may want to weigh information from both appendices when evaluating input from individuals with scientific and medical training.

Similarly, there is additional information in Appendix F which may contain additional input from individuals with scientific and medical training not captured in this appendix. The Board may want to weigh information from both appendices when evaluating impact to safety net providers.

Health Effects of Cosentyx

Individuals with scientific or medical training stated in public meetings and in survey responses that Cosentyx is a monoclonal antibody targeting an inflammatory mediator called interleukin 17A. It is an injectable biologic that is administered subcutaneously. Cosentyx is used to treat autoimmune inflammatory diseases such as psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-AxSpa), and hidradenitis suppurativa (HS). Cosentyx is also approved by the FDA to treat plaque psoriasis in patients 6 years or older, psoriatic arthritis in patients 2 years of age and older, and enthesitis-related arthritis (ERA).

Individuals with scientific and medical training reported in public meetings and surveys that Cosentyx provides the following beneficial health effects:

- Improved quality of life
- Amelioration of disease symptoms, such as inflammation of skin
- Lowered risk of comorbid health conditions
- Maintains disease in remission
- Improved psoriasis disease control and improved physical function
- Reduced back pain and improved mobility in AS and nr-AxSpa
- Prevention of irreversible joint damage and destruction

[1] The referenced small group meetings included discussion of multiple drugs currently undergoing affordability reviews by the Board, including Cosentyx.

- Reduced risk of flares in active enthesitis related arthritis
- Cosentyx is available in injectable subcutaneous and intravenous forms, providing patients with the option to choose the method that works best for them

Participants stated that Cosentyx is a first-line agent to treat moderate to severe PsA, HS, and PsO in patients without a history of inflammatory bowel disease. They stated that PsO symptoms can directly impact a patient's sleep, wellbeing, ability to complete daily living activities, and the social stigma of the condition can lead to depression and anxiety. Because PsO is a chronic condition, long-term management is necessary to keep disease activity under control and to lower the risk of developing other comorbid health conditions such as cardiovascular disease, mental health conditions, and metabolic syndrome. Treatment is highly individualized and dependent on many factors such as disease severity, location of active disease, and the presence of other comorbid medical conditions.

While Cosentyx is used to treat AS and nr-AxSpa, the utilization is lower due to the conditions being less prevalent. Additionally, utilization is lower in pediatric indications because PsO and PsA are rarer in children than in adults.

One participant stated they prescribe Cosentyx off-label for other forms of psoriasis, including palmoplantar pustular psoriasis. The participant also stated that Cosentyx is considered in the treatment algorithm for a rare skin condition called pityriasis rubra pilaris (PRP).

Side Effects

Individuals with scientific and medical training reported the most common side effects of Cosentyx as nasopharyngitis, which occurs in 1% of patients, allergic reactions, severe skin reactions that resemble eczema, and an increased risk of infections. Participants stated that before taking Cosentyx, patients should be evaluated for tuberculosis and patients with inflammatory bowel disease should be cautious before taking Cosentyx.

Therapeutic Alternatives

Individuals with scientific or medical training reported the availability of in-class therapeutic alternatives for Cosentyx, and that Cosentyx has an advantage over its therapeutic alternatives in that it is available intravenously. They stated that compared to Cosentyx, Humira may not be as effective and has more potential side effects. One participant said that while there are many topical and systemic treatment options for psoriasis, treatment is individualized for each patient. Individuals may not be candidates for therapeutic alternatives due to age, systemic medical diseases or history of malignancy, mental health conditions, other medications/medication interactions, allergies, lifestyle habits, and prior treatment failures or experiences with other psoriasis medications. Due to these factors, common therapeutic alternatives may or may not exist.

Financial Effects of Cosentyx

Individuals with scientific and medical training were asked three types of questions related to the financial effects of Cosentyx. Some survey questions and meeting discussions focused on better understanding patient out-of-pocket (OOP) costs for Cosentyx, while other survey questions and meeting discussions focused on better understanding the relative financial effects of Cosentyx on health, medical, or social services costs, and a third type of question aimed to better understand patient and provider experience with utilization management requirements. Information from all types of questions are summarized below.

Patient Cost and Relative Financial Effects

One participant stated that patients raise financial concerns about the cost of Cosentyx, and two others stated patients rarely raise financial concerns. Participants said they discuss plan formulary alternatives, plan specific cost of the drug, and manufacturer assistance programs with their patients. One participant stated that there are a variety of assistance programs to help support patients with affordability and that 74% of Colorado patients accessed Cosentyx through their commercial insurance using a copay card in 2022.

Utilization Management

Participants indicated utilization management policies, such as step therapy or prescription drug formulary tiers, have impacted their patients' ability to access Cosentyx. No further information was provided by participants on utilization management.

Audio from Public Meetings with Individuals with Scientific or Medical Training

The audio from the September 21, 2023 public Zoom meeting is found via the following link: https://us06web.zoom.us/rec/play/YhX2tV3_n42gEFJGCJm6UaVsybIykUUnUzUaiwy_ArmHq7C16Jf9Um7sRm19oU5GDH1nz2OgHfQknSW-.XhroK3sOpRk3Zu-l.

The Scientific or Medical Training Survey was live on the Prescription Drug Affordability Board website from September 12 to October 3. At the March 18, 2024 PDAB meeting, Board members requested more information from patients and voted to reopen the surveys from April 1 to April 30, 2024. Though survey results are not a representative sample of all individuals with scientific or medical training, the results can still provide important input from individuals with scientific and medical training.

Figure I-1
Individuals with Scientific and Medical Training Survey

Personal Information

I am answering this survey as an individual with scientific or medical training who mainly utilizes my expertise: *

- [ ] In research of this drug for prescription drug development for a manufacturer.
- [ ] In research of this drug in an academic setting.
- [ ] As a prescriber of this drug to patients.
- [ ] As a prescriber of this drug to patients in a safety net setting.
- [ ] Other:

My expertise directly relates to patients who live: *

- [ ] In Colorado
- [ ] Nationally
- [ ] Other:

Health Effects

Please list the conditions that are treated by the prescription drug for which you are providing expertise.

Your answer

Please list the conditions that are treated by the prescription drug for which you are providing expertise.

Your answer

From your experience, how is this drug used in standard medical practice?

Your answer

From your experience, describe any off-label usage of this drug.

Your answer

In your experience, what are the health benefits of this drug?

Your answer

In your experience, what are the health disadvantages of this drug?

Your answer

From your experience, are there any common therapeutic alternatives to this prescription drug? If so, please list them.

Your answer

In your experience, what are the benefits or disadvantages between therapeutic alternatives and this prescription drug?

Your answer

Financial Effects

In your experience, do patients raise financial concerns when being prescribed this prescription drug?

Your answer

Do you discuss this drug's expense with patients when prescribing?

- ◯ Yes
- ◯ No
- ◯ Not applicable

When do you discuss financial effects with patients related to this drug?

- ◯ At the point of prescribing.
- ◯ After the appointment, before the patient reaches the pharmacy.
- ◯ After the patient has been to the pharmacy.
- ◯ Someone else in my organization discusses financial effects with patients.
- ◯ I do not discuss financial effects with patients.
- ◯ Other:

At the point of prescribing, do you discuss any of the following with your patients related to this prescription drug? Select all that apply.

- [ ] Plan specific cost of the drug
- [ ] Patient deductible information
- [ ] Plan formulary alternatives
- [ ] Cost for uninsured patients
- [ ] Pharmacy specific pricing
- [ ] Manufacturer assistance programs
- [ ] Other:

In your experience, have utilization management policies (e.g., insurance requirements related to step therapy or prescription drug formulary tiers) impacted your patients' ability to access this drug?

- ◯ Yes
- ◯ No
- ◯ Other:

If you are a safety net provider, does your clinic/facility provide this prescription drug to patients? If not, why?

Your answer

Individuals with Scientific and Medical Training Results

Survey results are provided for Personal Information, then Health Effects, followed by Financial Effects.

Table I-1
Individuals with Scientific and Medical Training Survey Results
Personal Information, Health Effects, and Financial Effects

ID #	I am answering this survey as an individual with scientific or medical training who mainly utilizes my expertise:	My expertise directly relates to patients who live:	Which prescription drug are you providing comments on today?	Please list the conditions that are treated by the prescription drug for which you are providing expertise.	What is the impact of this condition(s) on your patients?	From your experience, how is this drug used in standard medical practice?	From your experience, describe any off-label usage of this drug.
1	As a prescriber of this drug to patients.	In Colorado	Cosentyx	Psoriasis	The appearance of psoriasis can be embarrassing. The symptoms associated with psoriasis, including itch, pain, flaking skin, can directly impact patient wellbeing, patient sleep, and ability to complete activities of daily living. Psoriasis is also well known to have systemic medical associations including metabolic syndrome, cardiovascular disease, mental health conditions like depression and anxiety, and psoriatic arthritis, a potentially debilitating inflammatory arthritis. Having active psoriasis can lead to decreased work productivity, decreased interpersonal relationships, and impact emotional wellbeing. Patients often feel the need to hide their skin with clothing or other accessories. In addition, psoriasis is a chronic condition, there is no cure, so long-term management to keep disease activity under control is necessary. Treatment can improve skin disease and it can also potentially lower the risk of developing other comorbid health conditions. Psoriasis	Cosentyx is a first-line agent to treat moderate to severe psoriasis in my practice. Cosentyx is also approved for moderate to severe scalp psoriasis and pediatric psoriasis down to age six. It is chosen to treat psoriasis patients who do not have a history of inflammatory bowel disease. It is approved for psoriatic arthritis and can be used to manage patients who have both skin and joint psoriatic disease.	I have prescribed Cosentyx for other forms of psoriasis, including palmoplantar pustular psoriasis, and refractory hidradenitis suppurativa. It is also considered in the treatment algorithm for a rare skin condition, pityriasis rubra pilaris (PRP).

					treatment is highly individualized and dependent on many factors including disease severity, location of active disease, and the presence of other comorbid medical conditions such as psoriatic arthritis, inflammatory bowel disease, history of malignancy, and depression and/or anxiety. Not all psoriasis patients respond to the same medications and oftentimes trying multiple different treatments before finding the one that works is needed. In addition, patients may lose response to a medication over time, and because again psoriasis is a chronic condition, they need to switch to another therapy. These situations can be frustrating to the patient, but we can also provide hope that multiple treatment options are FDA-approved and available (others are also being researched), and our goal is to find that one that works to control their disease.		
2	As a prescriber of this drug to patients.	In Colorado	Both	Psoriasis, Hidradenitis suppurative	Both conditions can have a huge impact on quality of life and have internal implications if not treated appropriately	Cosentyx for psoriasis, psoriatic arthritis and HS; Stelara for psoriasis, especially in kids	None
3	As a prescriber of this drug to patients.	In Colorado	Cosentyx	Psoriasis, psoriasis arthritis, ankylosing spondylitis	It is chronic conditions that can affect patients mobility and interfere with daily activities	Used frequently, standard of care for above mentioned conditions	N/a

ID #	In your experience, what are the health benefits of this drug?	In your experience, what are the health disadvantages of this drug?	From your experience, are there any common therapeutic alternatives to this prescription drug? If so, please list them.	In your experience, what are the benefits or disadvantages between therapeutic alternatives and this prescription drug?	In your experience, do patients raise financial concerns when being prescribed this prescription drug?	Do you discuss this drug's expense with patients when prescribing?	When do you discuss financial effects with patients related to this drug?	At the point of prescribing, do you discuss any of the following with your patients related to this prescription drug? Select all that apply.

1	The health benefits include improved psoriasis disease control which often leads to improved quality of life, amelioration of symptoms, and as above, psoriasis disease control can also potentially lower the risk of developing other comorbid health conditions. When treating psoriasis patients with psoriatic arthritis, it can prevent irreversible joint damage and destruction.	As with many systemic medications to treat psoriasis (biologic and traditional systemic medications), there is an increased risk of infections.	This is a challenging question to answer because while many topical and systemic treatment options exist for psoriasis, the individual patient must be taken into consideration. Psoriasis factors to consider include body surface area involved, skin locations affected, special site involvement, nail involvement, other psoriasis subtypes, and whether there is concurrent psoriatic arthritis. Individuals may not be candidates for therapeutic alternatives due to age, systemic medical diseases or history of malignancy, mental health conditions, other medications/medication interactions, allergies, lifestyle habits, and prior treatment failures or experiences with other psoriasis medications. Common therapeutic alternatives may or may not exist for the patient, depending on these factors.	As above, this is a challenging question to answer. All medications have risks and benefits but whether the benefits outweigh the risks for the therapy I choose, and their alternatives, depends on the psoriasis patient in front of me.	Yes	Yes	At the point of prescribing.	Plan formulary alternatives, Manufacturer assistance programs

ID #	In your experience, what are the health benefits of this drug?	In your experience, what are the health disadvantages of this drug?	From your experience, are there any common therapeutic alternatives to this prescription drug? If so, please list them.	In your experience, what are the benefits or disadvantages between therapeutic alternatives and this prescription drug?	In your experience, do patients raise financial concerns when being prescribed this prescription drug?	Do you discuss this drug's expense with patients when prescribing?	When do you discuss financial effects with patients related to this drug?	At the point of prescribing, do you discuss any of the following with your patients related to this prescription drug? Select all that apply.
2	Improve inflammation of skin and inside the body	Really not many unless a patient does not tolerate the med	Not common alternatives; for HS only other approved med is Humira and it does not work that well	Humira has more potential side effects and is not as effective	Not typically	Yes	Someone else in my organization discusses financial effects with patients.	Manufacturer assistance programs
3	It is important to maintain disease in remission and available in injectable subcutaneous and intravenous forms	N/a	We can use other medications, however if patients did not tolerate one group we move forward to different group of medication, the advantages of cosentyx that it can be used subcutaneously and intravenously	Some of them might not be effective for patient, copays, accessibility, not available intravenously	Rarely	Yes	At the point of prescribing.	Plan specific cost of the drug, Plan formulary alternatives, Manufacturer assistance programs

ID #	In your experience, have utilization management policies (e.g., insurance requirements related to step therapy or prescription drug formulary tiers) impacted your patients' ability to access this drug?	If you are a safety net provider, does your clinic/facility provide this prescription drug to patients? If not, why?	If you are a safety net provider, do you receive a 340B discount for this prescription drug?	In your experience, are there any other financial effects of the condition and prescription drug you think the Board should consider?
1	Yes			
2	Yes			
3	Yes	N/a	No	N/a

Appendix J

Cosentyx: Voluntarily Submitted Information

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide. (C.R.S. § 10-16-1406(4)(i)).

Rule: Information Voluntarily Submitted from a Manufacturer, Carrier, Pharmacy Benefit Management Firm, or Other Entity:

- The Board will consider information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity.
- Manufacturers, carriers, pharmacy benefit management firms, or other entities shall have 60 days from the date of selection to provide such information to the Board for its consideration. (3 CCR 702-9, Part 3.1.E.2.i).

Policy: Staff will prepare information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity for the Board's consideration.

- After selection of a prescription drug for affordability review, the Board will notify interested parties, including members of the PDAAC, using its listserv and by posting on its website, of the ability to submit information pursuant to section 10-16-1406(4)(i), C.R.S., if such interested parties are manufacturers, carriers, pharmacy benefit management firms, or other entities. (PDAB Policy 04, p. 8).

Underlying Methodology: None.

Data Source(s): All information that is voluntarily provided to the Board by Oct. 3, 2023 will be provided to the Board for consideration during affordability reviews. Board staff plan to summarize which entities submitted information and the nature of the submitted information.

Considerations and Data Limitations: Some voluntarily submitted information may be confidential, proprietary, or trade secret. Such data will not be made public and can only be discussed by the Board in executive session. Though the deadline for voluntarily submitted information is 60 days after selection (October 3, 2023), the Board voted to extend the voluntarily submitted information for patients and caregivers until October 12, 2023.

This component's information is voluntary. While the Board may request clarification of voluntarily submitted information, there will not be an assessment of the accuracy of voluntarily submitted information or the extent to which it applies to Coloradans. To the degree that voluntarily submitted information is different from information presented in other affordability review components, the Board will need to decide how to evaluate such discrepancies.

Cosentyx: Voluntarily Submitted Information Evidence

In compliance with Board policy, on August 10, 2023, Board staff emailed a listserv announcement to subscribers to the PDAB listserv and posted on an announcement on the PDAB website that interested parties had the ability to voluntarily submit information related to Cosentyx for 60 days following selection of Cosentyx for an affordability review.

Information from Manufacturer

Information from Other Entities

Proprietary Information

Novartis Services, Inc.
801 Pennsylvania Avenue
NW
Suite 700
Washington, DC 20004

Courtney Piron
US Country President
Head, US Public Affairs
Telephone +1 202-253-1803

October 3, 2023

VIA ELECTRONIC DELIVERY
Colorado Prescription Drug Affordability Review Board
1560 Broadway, Suite 850
Denver, Colorado 80202

Care of: dora_ins_pdab@state.co.us

Re: Selection of Cosentyx® for Affordability Review

Dear Colorado Prescription Drug Affordability Board ("Board"):

Novartis Services, Inc. submits this letter on behalf of Novartis Pharmaceuticals Corporation and its affiliates referred to collectively herein as "Novartis." We appreciate the opportunity to comment on the Board's selection of Cosentyx® (secukinumab) for affordability review pursuant to *Colo. Rev. Stat. § 10-16-1406*.

Novartis provides health care solutions that address the evolving needs of patients and societies worldwide. We are a focused medicines company concentrated on the core therapeutic areas of cardiovascular disease, immunology, neuroscience, and oncology. At Novartis, we are united by a single purpose to reimagine medicine to improve and extend lives. Through innovative science and technology, we address some of society's most challenging health care issues. We work to discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. Our vision is to be the most valued and trusted medicines company in the world.

At Novartis, we believe everyone should have access to the medicines they need. When we determine the prices for our medicines, we consider the value that these medicines provide to patients as well as health care systems and society at large.

Cosentyx is a proven medicine that has been studied clinically for more than 14 years and used to treat more than 1 million patients globally since its launch in 2015.[1] The medicine is backed by strong evidence supporting its safety and efficacy for patients across multiple autoimmune diseases, including moderate-to-severe plaque psoriasis, psoriatic arthritis (PsA), ankylosing spondylitis (AS),

[1] Data on file. COSENTYX Patient Reach. Novartis Pharmaceuticals Corp; January 2023.

and radiographic axial spondyloarthritis (nr-axSpA).[2,3,4,5,6,7,8] We believe Cosentyx is an important treatment option, and we offer a variety of programs to provide broad, affordable access for eligible patients. We remain confident in the value of Cosentyx and are committed to supporting those who can benefit from it.

Below we briefly summarize why the Board should recognize that Cosentyx is affordable and decline to move forward with consideration of an upper payment limit:

- Cosentyx is a proven medicine backed by robust evidence.
- Colorado patients have broad, affordable access to Cosentyx today. In fact, the vast majority of patients who access Cosentyx through commercial health coverage pay nothing out-of-pocket due to the Novartis co-pay support program available to eligible Cosentyx patients.[9] Many other moderate-income, lower-income, and underinsured patients pay nothing for Cosentyx via the Novartis Patient Assistance Foundation.
- The average net price of Cosentyx to payers has been nearly flat over the past five years. When adjusted for inflation, the average net price has declined.
- Cosentyx provides value to the broader health care system. This is particularly clear when compared to therapeutic alternatives.
- The imposition of an upper payment limit would raise serious policy concerns, including the potential impact to patient access. While the United States leads the world in access to lifesaving, innovative therapies, other jurisdictions where regulators impose price caps or other limits have traditionally lagged.[10]

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[2] Baraliakos X, Braun J, Deodhar A, et al. Long-term efficacy and safety of secukinumab 150 mg in ankylosing spondylitis: 5-year results from the phase III MEASURE 1 extension study. RMD Open. 2019;5:e001005.

[3] Bissonnette R, Luger T, Thaçi D, et al. Secukinumab demonstrates high sustained efficacy and a favourable safety profile in patients with moderate-to-severe psoriasis through 5 years of treatment (SCULPTURE Extension Study). J Eur Acad Dermatol Venereol. 2018;32:1507-1514.

[4] Mease PJ, Kavanaugh A, Reimold A, et al. Secukinumab Provides Sustained Improvements in the Signs and Symptoms of Psoriatic Arthritis: Final 5-year Results from the Phase 3 FUTURE 1 Study. ACR Open Rheumatol. 2020;2:18-25.

[5] Data on file. CAIN457F2310 (MEASURE 1 and 2): Pooled Safety Data. Novartis Pharmaceuticals Corp; July 23, 2018.

[6] Data on file. CAIN457F2310 and CAIN457F2305 summary of 5-year clinical safety in (ankylosing spondylitis). Novartis Pharmaceuticals Corp; May 2019.

[7] Data on file. CAIN457F2312 Data Analysis Report. Novartis Pharmaceuticals Corp; November 2008.

[8] McInnes IB, Mease PJ, Kirkham B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet 2015;386:1137-46.

[9] IQVIA Claim Data FY 2022, Jan-Aug 2023.

[10] PhRMA.com. Global Access to New Medicines Report. https://phrma.org/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world. Accessed September 25, 2023.

We have significant concerns with the methodologies and data used by the Board in its work, and fear these may yield an erroneous and unreliable result in affordability reviews. We urge the Board to pause its work while it addresses these issues and reformulates a reliable process.[11]

Our detailed comments are provided below.

A. Cosentyx Is a Proven Medicine for Patients Backed by Robust Evidence.

Cosentyx is indicated for the treatment of moderate-to-severe plaque psoriasis in patients 6 years of age and older who are candidates for systemic therapy or phototherapy. Cosentyx is also indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.

Affecting 7.5 million Americans, psoriasis is a chronic autoimmune inflammatory disease characterized by thick and oftentimes extensive skin plaques that cause itching, scaling, and pain. Psoriasis can negatively impact patients' quality of life, both psychosocially and physically.[12]

However, psoriasis is not simply a skin disease. Up to 41% of patients with certain types of psoriasis may also have psoriatic arthritis, which - through destructive inflammation - can lead to irreversible joint damage, if not properly treated.[13]

In clinical trials, Cosentyx has been shown to help achieve clear skin in plaque psoriasis and help stop progressive joint damage and improve physical function in patients with psoriatic arthritis. Cosentyx generally starts working in as little as 3 to 4 weeks, with positive results observed up through 5 years.[14]

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[11] Novartis is making this submission in accordance with the procedures provided by Colorado law and to show that Cosentyx is not unaffordable for Colorado customers. Novartis, however, has significant concerns about the legality of the Colorado statute that established the PDAB and by making this submission does not waive its rights with regard to any legal challenge to that statute.

[12] Armstrong A, Mehta M, et al. Psoriasis Prevalence in Adults in the United States. JAMA Dermatol. 2021 Aug; 157(8): 1–7. doi: 10.1001/jamadermatol.2021.2007.
National Psoriasis Foundation. About Psoriasis. https://www.psoriasis.org/about-psoriasis/. Accessed September 27, 2023.

[13] Rech J, Sticherling M, et al. Psoriatic arthritis epidemiology, comorbid disease profiles and risk factors: results from a claims database analysis. Rheumatol Adv Pract. 2020; 4(2): rkaa033. doi: 10.1093/rap/rkaa033.

[14] Cosentyx Prescribing Information. East Handover, NJ: Novartis Pharmaceuticals Corp; July 2023.
Cosentyx.com. Results with Cosentyx. https://www.cosentyx.com/psoriatic-arthritis/treatment-results. Accessed September 27, 2023.

Cosentyx is also approved for active ankylosing spondylitis and active non-radiographic axial spondyloarthritis – two inflammatory arthritis conditions that affect the spine - as well as active enthesitis-related arthritis (ERA).

We are further developing Cosentyx in other areas of high unmet need such as Hidradenitis Suppurativa (HS), a painful and often debilitating inflammatory skin condition; and giant cell arteritis (GCA) a condition that can cause pain and swelling in blood vessels.

B. Cosentyx Is Affordable for Coloradans.

At its core, the question of whether Cosentyx is "affordable" for Coloradans has a simple answer: the drug is affordable because the vast majority of Coloradans who access Cosentyx through commercial health coverage pay little or nothing at all for the drug. Additionally, pursuant to state and federal regulations, patients who access prescription drugs, including Cosentyx, through Colorado's Medicaid program pay only a nominal amount out-of-pocket.[15]

Furthermore, the health plans that pay a portion of the cost of Cosentyx benefit from heavily discounted prices. The complicated interplay of drug pricing and rebates throughout the supply chain and the selective use of pricing data can complicate what should be a straight-forward analysis of affordability.

Chief among these complicating factors is a reliance on "list" prices as a proxy for patient costs and affordability. A patient or health plan rarely if ever pays the list price of a drug. In Colorado, as in the rest of the United States, where third-party payers and government health care programs negotiate the price of drugs they buy, Novartis works with third parties to negotiate significant discounts on our medicines. The vast majority of patients, too, enjoy significant assistance even beyond the net price of Cosentyx and their insurance coverage through the Cosentyx Co-Pay Program or the charitable assistance of the Novartis Patient Assistance Foundation (NPAF). These programs further reduce the costs patients pay, often to as little as $0[16].

Ultimately, to accurately determine the affordability of Cosentyx to Colorado consumers, the Board must use the actual amounts paid by patients and the net, not list, price paid by payers.

Colorado Patients Often Pay Nothing for Cosentyx.

For patients, the most significant hallmark of "affordability" is the price they pay out-of-pocket. Patients judge the cost of a medicine not by reference to

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[15] Health First Colorado Co-Pays. https://www.healthfirstcolorado.com/co-pay/. Accessed September 27, 2023.
[16] IQVIA Claim Data FY 2022, Jan-Aug 2023.

complicated gross or net price formulas, but by how much they must pay out-of-pocket to access their medication.

For the vast majority of commercially-insured patients in Colorado, that price is **$0**.

The reason so many commercially-insured patients pay zero dollars for Cosentyx is because Novartis negotiates with third-party payers for affordable coverage for patients and provides a suite of programs to help address any residual affordability challenges once coverage is defined by payers. Through our Patient Assistance website[17], we help patients find programs that may provide savings or resources that can help them access Cosentyx or any other Novartis prescription medication. We do this because Novartis believes that medicines should be available to all who need them.

Novartis has a co-pay assistance program in the US that helps thousands of patients with commercial health coverage access our medicines at reduced cost to them. In 2022, 74% of Colorado patients accessing Cosentyx through their commercial coverage used a Cosentyx co-pay card. So far in 2023, 72% of these patients have used a Cosentyx co-pay card. Of these patients, 90% paid $0 out-of-pocket for Cosentyx. The remainder paid a nominal amount.[18]

This means nearly 3 out of every 4 Colorado patients accessing Cosentyx with commercial insurance in 2022 and 2023 to date paid nothing or nearly nothing out-of-pocket.

We summarize these results in the table below:

Colorado Patients Using Cosentyx: Commercial Insurance Only[19]	2022	2023[20]
Patients with Commercial Insurance	986	853
Percentage of Patients Using a Co-pay Card	74%	72%
Average Patient Payment After Co-pay Card is Applied	~$0	~$0

[17] Novartis.com. Patient Assistance. https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance. Accessed September 21, 2023.
[18] IQVIA Claim Data FY 2022, Jan-Aug 2023, SP Dispense Data FY 2022, Jan-Aug 2023.
[19] IQVIA Claim Data FY 2022, Jan-Aug 2023, SP Dispense Data FY 2022, Jan-Aug 2023. Claims data at patient and claim level from IQVIA gives visibility for each claim - the amount authorized and amount paid through the Novartis Co-pay card.
[20] Through 8/31/23.

Additionally, our “Covered Until You're Covered Program” is available for eligible patients who have commercial insurance, a valid prescription for Cosentyx, and a denial of insurance coverage based on a prior authorization request. The program provides Cosentyx for free to eligible patients for up to two years, or until they receive insurance coverage approval, whichever occurs first.[21]

Further, for patients who are uninsured or under-insured (commercially-insured or in government-funded insurance programs), NPAF provides Novartis treatments at no cost to eligible US patients who are experiencing financial hardship and have limited or no prescription drug coverage.[22] NPAF is an independent, 501(c)(3) non-profit, non-commercial entity. Patients who cannot afford the cost of their Novartis medication may be eligible to receive it from NPAF at no cost.

In 2021, NPAF provided more than $4 billion in free medicines to more than 127,000 patients in the U.S., covering 71 medicines from our portfolio. Over the last five years, through NPAF, medications valued at $13.5 billion have been made available to 445,000 patients at no cost.[23]

We caution the Board against relying on data from third-party sources, including the state’s All Payer Claims Database, that purports to indicate a patient out-of-pocket cost for Cosentyx. That cost may well have been borne by Novartis or the NPAF through the mechanisms described above.

Colorado Payers Benefit From Significant – And Growing – Discounts on Cosentyx.

Payers such as commercial insurers routinely negotiate discounts from the Novartis list price. These discounts lower the final “net” price of the drug significantly below the initial list price. Payers and employers in turn can pass these discounts on to patients, or use them in other ways, such as for lowering premiums, applying the discount to administrative costs, or other uses.

The growing gap between list and net prices generated by this practice fuels increasing confusion about the real price paid for drugs by the health care system. While industry critics focus on the rise in wholesale acquisition cost

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[21] The Covered Until You're Covered Program requires the submission of an appeal of a coverage denial within the first 90 days of enrollment in order to remain eligible. A valid prescription consistent with FDA-approved labeling is required. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Novartis.com Cosentyx Connect. https://www.cosentyx.com/all/cosentyx-connect-personal-support-program. Accessed September 21, 2023.

[22] Novartis.com. Patient Assistance. https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance. Accessed September 21, 2023.

[23] Novartis in Society 2021 US Report, available at https://www.novartis.com/us-en/sites/novartis_us/files/2022-03/220211-novartis-in-society-report-2021_0.pdf.

(WAC), also known as the list or gross price, the reality is that price increases are often outpaced by discounts and rebates to third-party payers and other channel intermediaries (e.g., wholesalers, pharmacies).

Novartis discounts and rebates to payers are important not just to understanding why Cosentyx is *currently* affordable to patients, but also why the Cosentyx net price has remained essentially flat over time, and actually declined when adjusted for inflation, despite WAC price increases over the same period. It is critical that the Board base its affordability determination on the net price. The Board must take account of these rebates and discounts, which are a significant component of Cosentyx's affordability.

Notably, between January 2018 and January 2023, inflation, measured by the CPI, was 21%. By our estimate this means there was a declining Cosentyx net price over this timeframe when adjusted for inflation. Additionally, the net price of Cosentyx represents a greater discount off the gross price, or WAC, than many therapeutic alternatives.[24]

Cosentyx is an Effective Drug for Multiple Indications that Provides Value to the Broader Health Care System.

In evaluating a drug's affordability, the Board must take account of its "relative financial effects on health, medical, or social services costs." In this regard, Cosentyx should be recognized as effectively treating multiple indications that would otherwise significantly limit patient health and impose major costs on the state.

The major indications for which Cosentyx is used[25] are associated with significant economic burden. We strongly urge the Board to consider the value Cosentyx provides in reducing the direct and indirect costs of these diseases to the workforce, communities, and overall health care system as described below.

Psoriasis:

Total direct and indirect costs associated with the disease have been estimated at $11.3 billion annually. [26]

A claims database from 31 self-insured employers (representing 5.1 million employees, their spouses, and dependents) during the period from 1998 to 2005 was used to evaluate both the direct medical and indirect work-loss costs

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[24] Based on Novartis analysis that utilized Analysource for WAC comparisons and SSR Health for discount comparisons.

[25] For this analysis, Novartis focuses on its approved indications for treatment of psoriasis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, and non-radiographic axial spondyloarthritis.

[26] NPF, National Psoriasis Foundation Statistics [Online]. 2015b. Available: http://www.psoriasis.org/research/science-of-psoriasis/statistics [Accessed November 17, 2015].

associated with psoriasis.[27] After multivariate adjustment, psoriasis patients demonstrated significantly higher direct and indirect costs compared to other patients.[28] Approximately 40% of the total cost burden was associated with work loss (i.e., indirect costs).[29]

Cosentyx is effective in relieving this burden. A health economic model was developed to demonstrate the cost-effectiveness of Cosentyx for patients with plaque psoriasis. The patient population of interest included adults diagnosed with moderate-to-severe plaque psoriasis who are candidates for systemic or biologic therapy. The model demonstrated that the cost per responder was lower for Cosentyx 150 mg and 300 mg than some leading therapeutic alternatives.[30]

Psoriatic Arthritis (PsA):

The total direct costs of PsA in the US have been estimated at $1.9 billion annually.[31] There are limited data on the indirect costs (e.g., lost productivity and absenteeism) attributable to PsA in the US; however, it was reported that total indirect costs account for approximately 52% to 72% of total costs.[32] The costs increase with deterioration of disease activity and decline in physical function.[33]

A health economic model explored the cost-effectiveness of Cosentyx for patients with psoriatic arthritis (PsA). The patient population of interest included adults diagnosed with PsA who are candidates for biologic therapy or apremilast. Cosentyx 150 mg and 300 mg had a lower cost per responder than some leading therapeutic alternatives.[34]

Ankylosing Spondylitis (AS):

A health economic model explored the cost-effectiveness of Cosentyx for patients. The patient population of interest included adults with active AS treated with a biologic. The cost per responder was lower for Cosentyx 150 mg than another leading therapeutic alternative.[35]

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[27] Fowler, J.F., Duh, M.S., Rovba, L., Buteau, S., et al. 2008. The impact of psoriasis on health care costs and patient work loss. *J Am Acad Dermatol.* 59(5), 772-780.
[28] *Id*.
[29] *Id*.
[30] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[31] Lee, S., Mendelsohn, A. & Sarnes, E. 2010. The burden of psoriatic arthritis: a literature review from a global health systems perspective. P T. 35(12), 680-689.
[32] *Id*.
[33] *Id*.
[34] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[35] *Id.*

Non-radiographic axial Spondyloarthritis (nr-axSpA):

The economic impact of work limitations related to *nr-axSpA* is substantial and compounded by the typically young age at diagnosis.[36] Patients treated with Cosentyx showed substantial reduction in work-related impairment, measured through mean change in the Work Productivity and Activity Impairment (WPAI) from baseline to Week 52.[37]

Juvenile Idiopathic Arthritis (JIA):

Several studies have found that patients with JIA of all types have higher health care resource utilization and health care costs than patients without JIA.[38] [39] [40] As one of the most common chronic conditions in children, JIA places a sizable burden on the pediatric healthcare system and can result in a substantial economic burden for patients and their families. JIA includes several disorders in children involving inflammation of the joints. Cosentyx is approved to treat two of those disorders: ERA and juvenile PsA.[41]

C. The Board Should Defer Affordability Reviews This Year and Instead Address the Methodological and Implementation Issues With Its Processes.

Any determination by the Board that a drug is unaffordable, let alone the adoption of a UPL, would be a momentous step, and should come only after a deliberate, transparent, and cautious process. Reflecting that gravity, before moving forward with affordability reviews, the Board should first consider and correct the many methodological concerns that remain with its process and that prevent the public from having confidence in the Board's conclusions.

Unfortunately, the Board's process to date has revealed that many issues have yet to be firmly resolved. The lack of clarity and resolution lends an air of arbitrary unfairness to the process, which threatens to render its decisions and actions methodologically suspect.

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[36] Strand, V. and Singh, J. A. 2017a. Patient Burden of Axial Spondyloarthritis. *Journal Of Clinical Rheumatology : Practical Reports On Rheumatic & Musculoskeletal Diseases*. 23(7): 383-391.
[37] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[38] Krause ML, Zamora-Legoff JA, Crowson CS, Muskardin TW, Mason T, Matteson EL. Population-based study of outcomes of patients with juvenile idiopathic arthritis (JIA) compared to non-JIA subjects. *Semin Arthritis Rheum*. 2017;46(4):439-443.
[39] Kumar N, Ramphul K, Ramphul Y, et al. Children hospitalized for juvenile arthritis in the United States. Reumatologia. 2021;59(4):270-272.
[40] Marshall A, Gupta K, Pazirandeh M, Bonafede M, McMorrow D. Treatment patterns and economic outcomes in patients with juvenile idiopathic arthritis. Clinicoecon Outcomes Res. 2019;11:361-371.
[41] Angeles-Han ST, Ringold S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Screening, Monitoring, and Treatment of Juvenile Idiopathic Arthritis-Associated Uveitis. *Arthritis Care Res (Hoboken)*. 2019;71(6):703-716.

We recommend that the Board take this first year's selection process as an opportunity for learning and reflection. The Board can then identify lessons learned, revise its regulations or policies, and conduct a more transparent selection process next year without the clouds that have overshadowed this year's process.

We support the comments made by our trade associations PhRMA, BIO, and the Colorado Bioscience Association regarding areas demanding improvement. Novartis would like to bring the Board's attention specifically to the following gaps:

The Board's Comment and Deliberation Timeline Does Not Permit Meaningful Public Comment at All Stages.

The Board has designed a process that "front loads" all opportunity for public comment. The timeline adopted by the Board required written comments to be submitted by October 3, 2023. For the first cohort of affordability reviews, the Board will conduct deliberations scheduled for October 27, December 8, and sometime between December 11 and 15, 2023. For the second cohort, which will include Cosentyx, the Board will conduct deliberations scheduled for January 19, March 1, and sometime between March 4 and 8, 2024.

These deliberations will include review of information pertaining to the fourteen components required to be considered by the Board to determine affordability. While there will be opportunity for public comment at each of these deliberations, stakeholders have been informed that the Board will not consider those comments in affordability reviews. Further, all stakeholder meetings for each of the selected drugs occur prior to the scheduled deliberations.

Here, the Board has conceived of a process where the public only submits information, and the Board acts upon it with no further engagement. That process leaves no room for the public to correct inaccurate information or otherwise react to the Board's deliberations and its resulting conclusions.

Instead of what is currently scheduled, the Board should consider itself in conversation with the public. The board should schedule additional opportunities for stakeholder input *after* the Board publicly deliberates. And the Board should offer an opportunity for stakeholders to submit written comments on draft affordability review reports before they are final.

The Board is Acting on Incomplete APCD Data that the Public Cannot See.

The Colorado All-Payer Claims Database (APCD) is the single source that the Board will utilize to determine the number of patients receiving the drug, out-of-pocket costs incurred by patients, total amount paid for the drug, and the average amount paid per person per year. These four, of a total of five, selection criteria

comprise 77% of the weighted prioritization in selecting drugs that will be reviewed for affordability.

Per the Board's policy, stakeholders are unable to access the APCD data used to produce the 2023 Eligible Drug Dashboard, making a mystery out of the selection criteria and process. This decision to withhold the data also invites errors. It is generally accepted that there is no flawless system for collecting health care data. The APCD is not the exception. By masking this data from public scrutiny, the Board has multiplied the chances that it is relying on flawed data that a public review could easily correct.

Further, there are some structural errors in APCD data that are known to all. For example, APCD data does not include claims data for uninsured Coloradans and some commercial payers, who may be utilizers of selected drugs and beneficiaries of other assistance programs. Yet the Board is moving forward with an APCD-based analysis knowing this information is missing.

Additionally, the Board used 2021 data from the APCD to inform its selection of drugs because it was the most recent year for which complete claims data was available from the APCD.[42] This means the Board based its drug selection on at least some data that do not accurately reflect Colorado's 2023 marketplace.

Because APCD data are heavily shaping the Board's decisions, the Board should provide an opportunity for stakeholders to verify these data prior to the release of a draft affordability report for any drug. This will increase transparency in the review process and give stakeholders the opportunity to correct errors. Preventing stakeholders from doing so risks leaving the Board's analysis and resulting conclusions uncorroborated by other primary data sources.

Manufacturers Should Have an Opportunity to Review the Board's Net Price Estimates.

The Board intends to use SSR Health data to estimate rebates and the resulting net price of therapies and to discuss its findings in closed, executive session only. The Board has provided no guidance to the public on which SSR Health data sets will inform its net price estimates. This is concerning because SSR Health can customize a data set for a user in a number of ways, including allowing users to decide to include or omit certain payer segments, such as Medicaid.

While we appreciate the Board's intent in reviewing net pricing and other proprietary data in executive session, the Board should provide a mechanism for manufacturers to review and verify the SSR Health data that the Board will rely

[42] PDAB Staff Memo on Eligible Drug Identification Methodology. June 6, 2023. Available at https://drive.google.com/drive/folders/1RPJj2q7wBGAkJpyPSC7XzdHWGgdCHQkw.

on in its analysis. While SSR Health provides an estimate of a drug's per unit net price[43], manufacturers such as Novartis have their own financial data that reflect the precise revenue, rebates, and volume of their drugs.

We encourage the Board to provide an opportunity for manufacturers to review SSR Health rebate information for their drug and give priority in credibility to manufacturer-submitted rebate information submitted confidentially over the rebate estimates generated by SSR.

The Board Is Not Meeting with Manufacturers in Executive Session.

Manufacturers such as Novartis hold important but proprietary data relating to drug pricing and rebates and companies' investments in patient support.

But the Board should not be content to merely review a written submission on this key information and should instead actively engage in confidential executive session discussion with manufacturers to fully understand and contextualize these proprietary data.

We understand no such executive session meetings with manufacturers are contemplated, in light of perceived restrictions of the Open Meetings Law. But the Board's authorizing statute specifically permits it to meet in executive session "to discuss proprietary information,"[44] so long as it does not take final action in the session or vote to establish a UPL. And, if the law does *not* permit executive session discussion with manufacturers, that may well indicate a critical flaw with the statute that should be remedied by the legislature before the Board proceeds further with affordability reviews.

The Board Has Not Defined "Unaffordable."

The Board is required in its affordability analysis to determine if a drug is "unaffordable for Colorado consumers." Yet, neither the Board nor the legislation authorizing its review clearly define what "affordable" or "unaffordable" mean.

This striking gap leaves Novartis and the public with no understanding of what principles the Board is applying to reach its ultimate conclusions, and no means of verifying that the Board's analysis has been conducted correctly. Compounding this uncertainty is that the Board's regulations detail at great length the types of factors the Board might consider in its analysis, without specifying the relative weight or impact of any one factor.

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[43] As the Board's staff recently noted in its September 15, 2023 "Affordability Review Component Methodologies" memo, SSR data is an "estimate" that "may not reflect the actual rebates between manufactures and Colorado carriers or PBMs."
[44] C.R.S.A. §§ 10-16-1404(3).

Ultimately, the Board appears poised to make an *ad hoc* determination of whether a drug is "affordable" without clearly articulating what affordability would look like.

A Declaration of "Unaffordability" and the Resulting Imposition of an Upper Payment Limit Raises Serious Policy Concerns.

We have serious concerns about any manufacturer's ability to carve out an entire state from the current pharmaceutical pricing and supply chains so as to implement special pricing for one out of 50 jurisdictions. It is not clear if any implementation mechanism currently exists in the complex web of pricing and rebates to efficiently or accurately carry out a Colorado UPL. Before imposing a UPL, the Board should hold hearings and consult experts and the public about whether that UPL can actually be implemented.

Additionally, the Board should be cautioned that a UPL could have serious implications for Coloradan's access to therapies. Today, the United States leads the world in access to lifesaving, innovative therapies. Other jurisdictions where regulators impose price caps or other limits have traditionally lagged. For example, the US has access to 85 percent of all medicines launched from 2012 and the end of 2021, but only 61 percent of these medicines are reimbursed by public insurance plans in Germany, 60 percent in the U.K., 48 percent in Japan, 43 percent in France, 24 percent in Australia, and 21 percent in Canada.[45] We ask the Board to tread carefully in pricing, so as to keep the United States in its position of primacy and keep pharmaceutical innovation flowing to Coloradans.

D. Novartis Pending Intravenous Formulation of Cosentyx Should Be Excluded from the Affordability Review Process and Consideration of an Upper Payment Limit.

Novartis is proud that it has invested resources into developing a new intravenous (IV) formulation of Cosentyx. The FDA has assigned a PDUFA date for the IV formulation of Cosentyx of October 6.

The Board's Affordability Review Policy and Procedure document notes that "brand-name drugs and biological products will be identified for eligibility by identifying, consolidating, and listing NDCs with the same brand name, active ingredient, formulation, and dose." The Board thus recognized that brand-name drugs and biologicals approved under distinct formulations should be analyzed distinctly as part of any affordability review process.

Because the Cosentyx IV formulation has not yet been approved or marketed, no historical data, pricing or otherwise, exists for the new formulation. As a result,

[45] PhRMA.com. Global Access to New Medicines Report. https://phrma.org/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world. Accessed September 25, 2023.

we expect the Board to omit the Cosentyx IV formulation, if approved by the FDA, from the affordability review process and any subsequent consideration of a UPL.

Conclusion

For the reasons detailed above, Cosentyx is affordable to patients. The Board should reject the premise that it is not and decline to move forward with consideration of a UPL. We welcome the opportunity to answer any questions you may have about the information provided above. Please contact me at courtney.piron@novartis.com.

Sincerely,

Courtney Piron
US Country President
Head, US Public Affairs

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

September 30th, 2023

Colorado Division of Insurance
1560 Broadway, Suite 850
Denver, CO 80202

RE: Colorado Prescription Drug Affordability Board (CO PDAB) Voluntary Information Submission - Patient/Caregiver and Patient Organization Engagement for Consideration During Affordability Reviews

Dear Prescription Drug Affordability Board Members,

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is excited about the opportunity to participate in your drug affordability reviews. As such, we had patient representatives participate in all three public comments sessions relevant to our community (Enbrel, Stelara, and I - as a person on Cosentyx - was a participant) and shared the survey with many in Colorado and nationwide.

We appreciate how much the PDAB worked to include patients and associated testimony. As people who did participate, we would like to take this opportunity to provide feedback for the Board to review prior to your review. We hope you will consider our suggestions as you continue navigating this process.

About AiArthritis. We are the only patient organization in the world focusing solely on this group of diseases, whose leadership consists of those diagnosed with or caring for persons with our diseases, and who specialize in designing innovative, patient-inspired solutions. Our leaders are also public policy, education, and research experts. Given the evolving landscape of health affordability and economic assessments to request direct patient voice participation, in conjunction with the need to fine tune the associated processes, AiArthritis feels positioned to help.

The following comments are divided into two sections: Participation Feedback and General Process Comments.

Participation Feedback

- **Preparation Assistance.** Given new processes breed confusion and questions, there is no surprise Patient Organizations (who were largely responsible for getting the word out to potential patient participants) were unclear about participation (i.e., "Can patient organizations representing the patient voice participate, or only those diagnosed/care partners?" or "How would a patient prepare for participation in an online session?"). The Office Hours, hosted by Callie Shelton and Lila Cummings, were exceptionally helpful addressing these questions. They were equally available and willing to answer additional questions via email outside of scheduled office hours.

Recommendations: Continue the open office hours. Create and publish a FAQ document based on inquiries this initial round.

- **Participation of patients and care partners.** AiArthritis, as an organization who connects patients/care partners to opportunities to have a voice in matters that impact their health,[1] is excited about the evolving landscape to bring more people with lived experience to the conversation. In saying this, our organization is led by those affected by these diseases. We also understand challenges associated with inviting community participation *(i.e., they may feel uncertain they are answering the question correctly, uncertain how their perspectives will be interpreted, not fully clear of the purpose for participation/broader issue, fine line between wanting help developing speaking points and feeling 'scripted')*. While this is not the case with advocates, who are used to speaking publicly, there is a push to bring additional patients 'to the table,' including those who historically are not accustomed to sharing their stories or perspectives.

  Identifying patients/care partners who reside in Colorado, and taking or have taken a specific drug for an indicated disease, has proved difficult. AiArthritis and other organizations struggled to locate people to participate, particularly in online sessions. While part of the challenge likely involves known participatory barriers (as outlined above), there is concern how patient/care partner data will be included if the representation was small. *Note: We are uncertain how many patients/care partners participated via survey or email, but this information will be important to understand when planning for future reviews.*

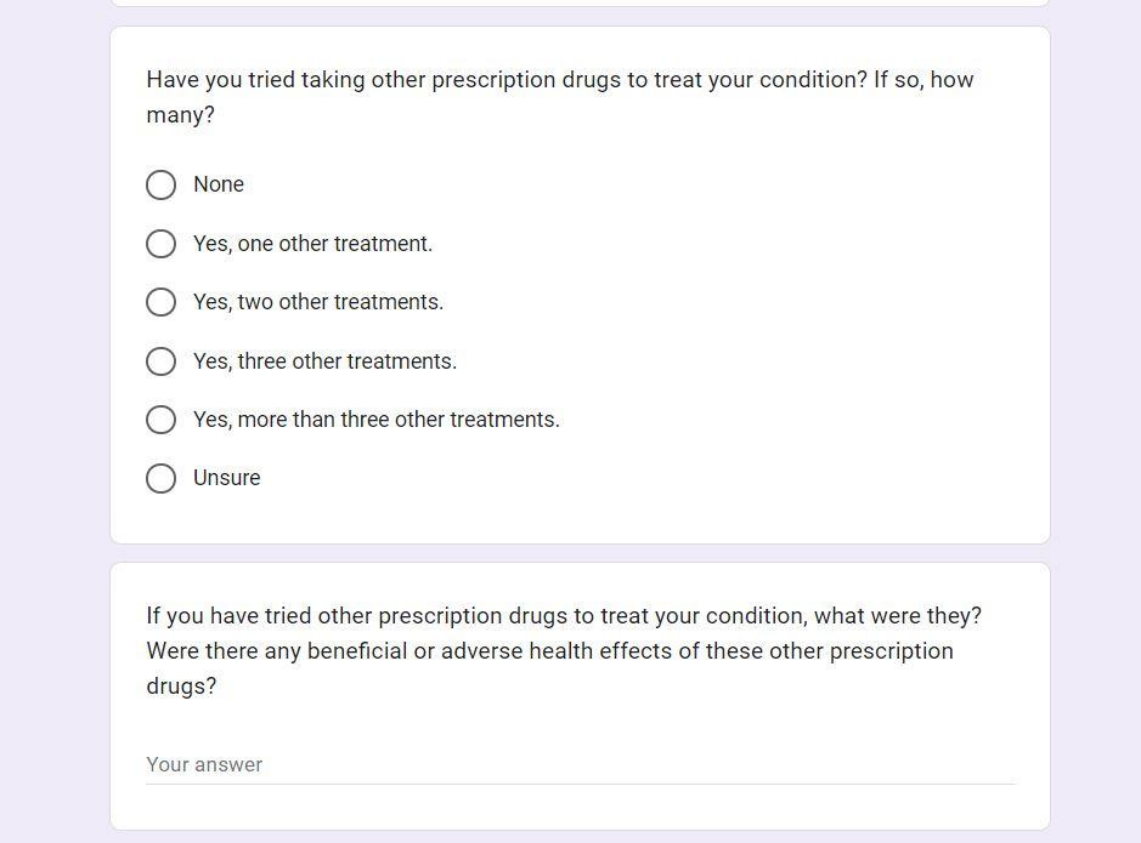
    - **Colorado residents versus those not residing in Colorado**. We appreciate the Board's willingness to permit non-Colorado residents to participate, particularly given that identifying Colorado participants was challenging. However, how their testimony will be weighted is unclear.

  Recommendations: We encourage the Board to release data collected from surveys and email participation, including demographic information, to access participatory challenge and guide efforts to recruit patient/care partner participants. If the percentage of CO participants is low (and additionally, what is considered 'low' should be established), future PDABs should increase outreach efforts to ensure sufficient participation.. Examples may include designing brochures or invitations to share with patients/care partners, Patient Organizations, clinics, or health practitioners.

- **Survey and associated polling design.** AiArthritis is pleased the Board considered many ways to capture patient/care partner perspectives. However, we are concerned about the question design, which may have resulted in inaccurate data collection.

[1] https://www.aiarthritis.org/aiarthritisvoices

- For example, one series of questions asks if a patient ever skipped a dose or stretched out a dose *due to drug affordability issues*. Patients may answer 'yes' to this question if they have skipped a dose or stretched out a dose, dismissing the 'why' at the end of the sentence. *However, as heard several times in the online sessions, this often occurs due to disruption in care caused by utilization management practices (i.e., prior authorization, step therapy) or formulary changes (including non-medical switching).* This is particularly true if the patient participates in the drug manufacturer's assistance plan.
- The following questions were asked in the survey version and discussed in the online sessions:



For those living with AiArthritis diseases and on biologic treatments, answering these questions could cause Board reviewers to feel, "Well, this person has done well on other drugs, so there is no real reason this one drug they are doing well on (or did well on for years) is that valuable." *That is not what Board reviewers should take away from this data.*

What the Board needs to understand is that the current practice of finding the treatment that will work best for us is often a long process. When it works, our disease is not progressing, comorbidities are not forming, and we are living our best lives. The number of times we tried another drug is irrelevant. The number of times it worked or did not work is irrelevant. What matters is finding one that works and, if it fails naturally - not if the

insurance company pulls a patient off of it for company gain - finding another one that works. This is the only way to avoid unnecessary disease activity and potentially permanent damage.

It may take between 1 and 9 years for a patient to get diagnosed, depending on several factors (failure to be referred to a specialist, dismissed due to negative blood work, etc.). After 6-12 months from onset, the window of opportunity to achieve remission closes without proper treatment. Once on a biologic, it can take three months or longer to realize if it will work. If not, the trial-and-error process continues. In the meantime, the patient is dealing with pain, fatigue, brain fog and other symptoms that compromise their ability to lead full, functional lives. But then it happens - the one drug that works. Suddenly, the patient may be able to work full time again, go to school regularly, or do simple things like carry their child or attend a ballgame

Biologics will not work for all people with a shared diagnosis. The goal is to find the right one, and hang on to it until it stops working on its own - as it may be years before another works. So whether a person tried and failed three and two worked or failed five and three worked, the data does not matter. *The only data that matters is if a patient is stable now and, if so, don't disrupt it.*

Recommendations: The Board should consider recruiting patients during the development of questions to identify potential issues prior to publication. Patients can identify issues that a person not living with the condition would not realize. The Board should consider the uniqueness of AiArthritis diseases and the associated challenges patients face to find the right treatments (outside of affordability factors).

- **Lack of other stakeholder participation.** Similar to our concerns regarding lack of patient/care partner participation (particularly from the state of Colorado), we are equally concerned regarding the lack of physician/health professional participation.

  Additionally, while we understand the movement towards involving the voices of only those diagnosed with diseases and who have real world experience using the treatments in review, Patient Organization's bring a perspective that could help ensure data collected is viewed with the proper context. For example, the average patient/care partner may not have supplemental references that show how long on average it takes to be diagnosed or how subgroups within diagnoses matter.

  Recommendations: AiArthritis suggests polling healthcare specialists who prescribe the drugs under review to inquire why they would or would not participate (in the case of our diseases, this could be led by groups like the Coalition of State Rheumatology Organizations/CSRO). We also suggest inviting representatives from Patient Organizations to the listening sessions and then offering them an

opportunity to meet with Board representatives to weigh in on patient/care partner comments, specifically to add context or supplemental information.

- **Disclosures and clarification**. AiArthritis understands there is concern from certain parties that involvement of Patient Organizations who are funded by the manufacturers of the drugs in review could be biased in their testimony, guidance, or feedback. While it is true that organizations, including AiArthritis, obtain financial support from pharmaceutical companies, they are not permitted to (nor do they try to) influence our voice.

  Recommendations. If there is any question regarding who influences Patient Organization perspectives, as clearly outlined in these submitted comments, the people affected by the conditions we serve- who are at the heart of our missions - influence our words.

General Process Comments

- **Regarding upper limit payments.** We understand the Board has the authority to review prescription drug costs and evaluate their impact on Coloradans through affordability reviews of prescription drugs. As a result of these reviews, the Board may then recommend ways to address those costs, which may set an upper payment limit for certain prescription drugs.
  - We question how this process may deter innovation and the development of new pharmacologic therapies. There are many people affected with AiArthritis diseases who have exhausted all current medications and are waiting for new treatments to surface.
  - We also are unclear how this will impact the introduction of biosimilars to the market and how the reference drugs may be impacted.
  - We question how precision medicine will be factored into this process, as we are beginning to identify which types of biologics may or may not work best for different subgroups.
- **How much will patient/care partner perspectives be considered in determining affordability?**
  - In the introduction to the survey, it states, "The PDAB will use the information you provide as part of the affordability review process to determine if a prescription drug is unaffordable for Colorado consumers." At least during the live sessions (as we have not viewed the survey data), patients overwhelmingly agreed Enbrel, Cosentyx, and Stelara were affordable if accessed with help from the manufacturer; but could be inaccessible and even cause harm as a result of insurance practices. How will these perspectives be counted and weighted?
    - Given the difficulty to recruit patients/care partners in Colorado, we are grateful the Board opened comments to a broader population. However, how will the data collected outside of the state be considered during the review?

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

In closing, I would like to extend gratitude again on behalf of AiArthritis, and all persons living with our diseases, for this opportunity to participate in your review process and to provide comments that we hope can help as you evolve it. Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

October 11, 2023

Gail Mizner, MD
Colorado Division of Insurance
1560 Broadway, STE 850
Denver, CO 80202

Dear Chair Mizner,

We are writing with regard to implementation of the Prescription Drug Affordability Review Board and concerns about the Board's possible use of biased and discriminatory measures of cost effectiveness. When Colorado passed legislation in 2021 creating the Board, we supported the protection against discrimination in the legislation[1] stating that the Upper Payment Limit for selected drugs "shall not consider research or methods that employ a dollars-per-quality adjusted life year, or similar measure, that discounts the value of a life because of an individual's disability or age." At the time, advocates testified to the Board calling for clear guidance that QALYs and similar measures are not allowable in Board considerations related to determining the selected drugs or establishing an upper payment limit. Clear guidance from the Board was not given.

Today, we are deeply concerned that the Board has specifically engaged consultants that have actively promoted the use of quality-adjusted life years (QALYs) and similar measures such as the equal value of life year gained (evLYG). The state has now selected five drugs to be reviewed for a possible Upper Payment Limit: Enbrel (rheumatoid arthritis), Genvoya (HIV), Cosentyx (psoriasis, psoriatic arthritis), Stelara (ulcerative colitis), Trikafta (cystic fibrosis). During the selection process, presentations from contracted entities to the Board related to selecting drugs included reference to the use of QALYs and similar measures. This is concerning, particularly as the Board moves to its economic analysis of the selected drugs.

We have learned from members of the PDAB staff that the Board will be reviewing numerous reports and analyses of the pricing of the drugs selected for review. We hope that the Board will transparently share the evidence base for decisions related to the selected drugs so it is clear to what extent evidence was used referencing QALYs or similar measures such as the evLYG, that discriminate against people with disabilities, older adults, and people with chronic conditions.

We are concerned that Colorado has contracted with the Program on Regulation, Therapeutics, and Law (PORTAL[2]), which we know to have a subcontract with the Institute for Clinical and Economic Review (ICER) for its work with the Massachusetts Health Policy Commission. ICER is well known for its use of the QALY and evLYG, calling the QALY the "gold standard" for value assessment of health care. PORTAL's independent work also routinely references the QALY and

[1] https://leg.colorado.gov/sites/default/files/2021a_175_signed.pdf
[2] https://www.linkedin.com/in/portal-research/

discriminatory methods of cost-effectiveness analysis. Presentations[3] (including from PORTAL) to the Colorado Board have referenced the use of a cost-per-QALY or and the evLYG in estimating cost effectiveness of treatments, leading us to be particularly concerned that these metrics may have influenced how Colorado selected the drugs for review. We are similarly concerned that the assessment toward an Upper Payment Limit for these treatments may involve reference to ICER studies, potentially using their evLYG calculations, which have been widely critiqued for failing to account for quality-of-life improvements and for being calculated using the QALY's flawed health utilities[4].

We were pleased to see several commenters[5] raise concerns about the Board's potential use of cost effectiveness analyses:

- Arthritis Foundation[6]: "However, data inputs used to calculate QALYs do not holistically reflect patient experiences, preferences, goals and benefit-risk tolerance."
- NORD[7]: "Complexities associated with rare disease therapies and the available data to determine their cost-effectiveness create unique challenges for determining fair prices for these products."
- Rare disease orgs[8]: "We are writing out of concern that some decisions made by the Prescription Drug Affordability Board (PDAB) could have a severely detrimental effect on families struggling with rare and severe diseases, making it more difficult for them to have access to the therapies they need and slowing the critical research that offers them the promise of a better life."
- U.S. Hereditary Angioedema Association[9]: "In our experience, efforts by payers to assess value and cost for the HAE community rarely consider the disability, death, pain, and fear associated with the condition."

As you may know, the U.S. Department of Health and Human Services (HHS) Office for Civil Rights recently issued its proposed rule implementing Section 504 of the Rehabilitation Act which ensures that people with disabilities will not be "excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency. The rule raised concerns about the use of value assessment and its potential for discriminatory decisions that restrict access to care, explicitly calling out several ICER reports. As part of its proposed rulemaking on Section 1557 of the Affordable Care Act, HHS also requested comments on value assessment methods and the extent to which certain methodologies discriminate. Transparency of the evidence based used to make

[3] https://drive.google.com/drive/folders/1xhVdm0P8mm1sbybuyjU6bXSbWV5YFD6K
[4] https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf
[5] https://drive.google.com/drive/folders/1_m3oapRlN3jHhwue-7PBYQc3vrwClkQm
[6] https://drive.google.com/file/d/1HnebNIaV78rtWKrqXkhE4vroogNE2ovM/view?usp=drive_link
[7] https://drive.google.com/file/d/1suGN0JwBzyETveDmJ4KHhEdvbfOrva-w/view?usp=drive_link
[8] https://drive.google.com/file/d/1_mHb6e3zOXDRfjcBWZuI2Ez_hPtDsIqz/view?usp=drive_link
[9] https://drive.google.com/file/d/1ioFJjkyJ_1xIlUrQ0-EH8uoQBqWP7vez/view?usp=drive_link

decisions is essential to allow for appropriate oversight of federal and state program activities and to prevent discrimination.

We urge the Board to advance a clear policy against the use of QALYs and similar measures consistent with the statute's intended protection. We also urge the Board to commit to transparency and to sharing the evidence on which it is making decisions so that the public can meaningfully provide input on its decisions.

Sincerely,

Siri Vaeth, MSW
Executive Director
Cystic Fibrosis Research Institute
svaeth@cfri.org

Sara Froelich
Executive Director
Chronic Care Collaborative
sara.froelich@ccc-co.org

Maggie Acuna
State Advocacy Associate Director
Crohn's & Colitis Foundation
macuna@crohnscolitisfoundation.org

Lucy Laube
State Government Relations Manager West
National Psoriasis Foundation
llaube@psoriasis.org

Thayer Roberts
Deputy Director
Partnership to Improve Patient Care (PIPC)
thayer@pipcpatients.org

Adrienne Shapiro
Co-Founder
Axis Advocacy
Adrienne@axisadvocacy.org

Kathleen Arntsen
President & CEO
Lupus and Allied Diseases Assoc. Inc.
kathleen@ladainc.org

Michael Eging
Executive Director
Rare Action Access Project
mike@rareaccessactionproject.com

Jeffrey Anders
Color of Crohn's and Chronic Illness
Jeffreyanders7@gmail.com

Katherine Perez, JD
Director
The Coelho Center for Disability Law,
Policy and Innovation
katherine.perez@lls.edu

Matt Pagnotti
State & Local Government Relations Director
Vivent Health
matt.pagnotti@viventhealth.org

Monica Dudley-Weldon, MSc
President
SYNGAP1 Foundation
Monicaw@syngap1foundation.org

Lisbet Finseth
Senior Manager of Advocacy
National Multiple Sclerosis Society
Lisbet.Finseth@nmss.org

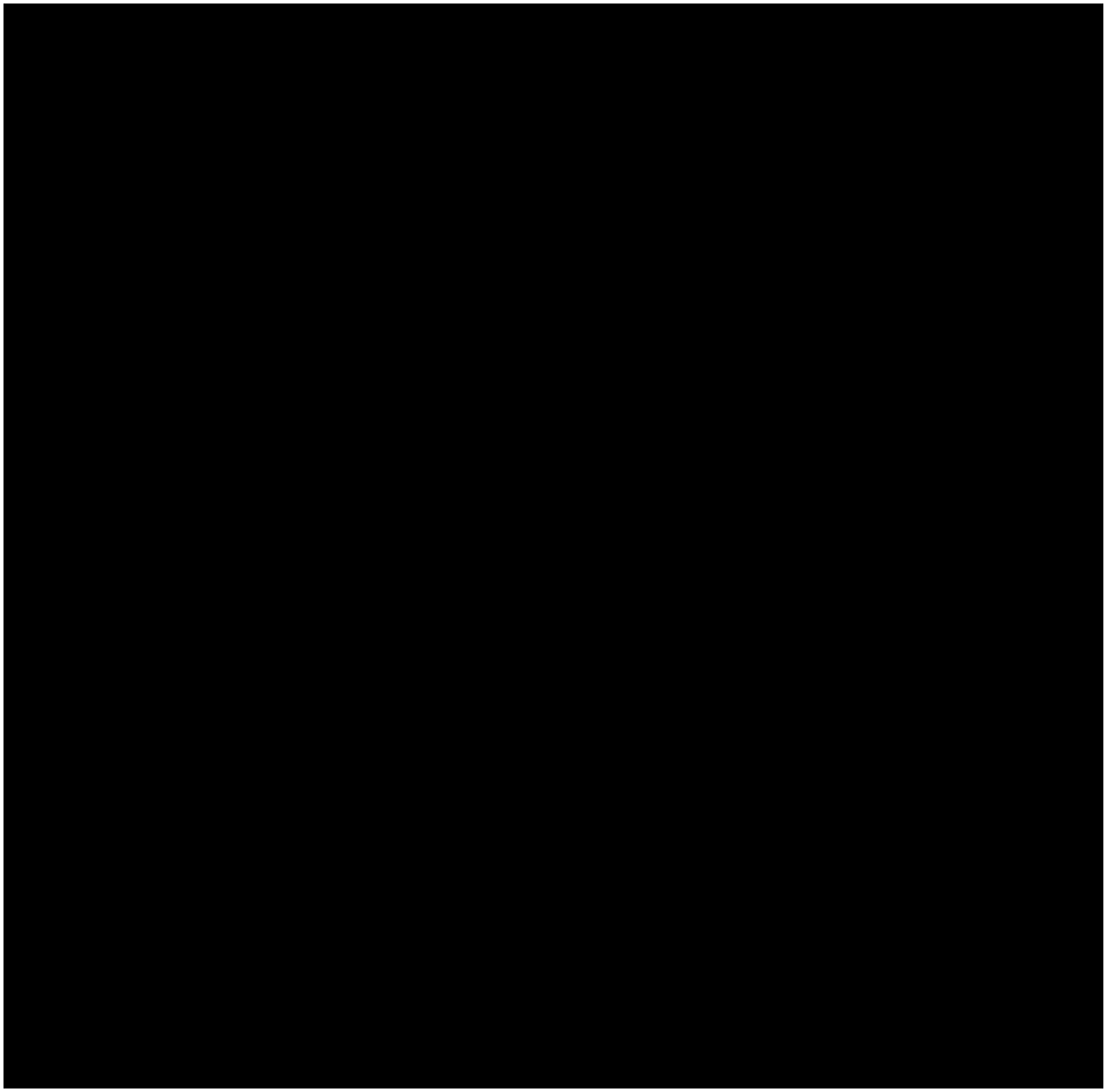
Kathleen Arntsen
President & CEO
Lupus and Allied Diseases Association, Inc.
kathleen@ladainc.org

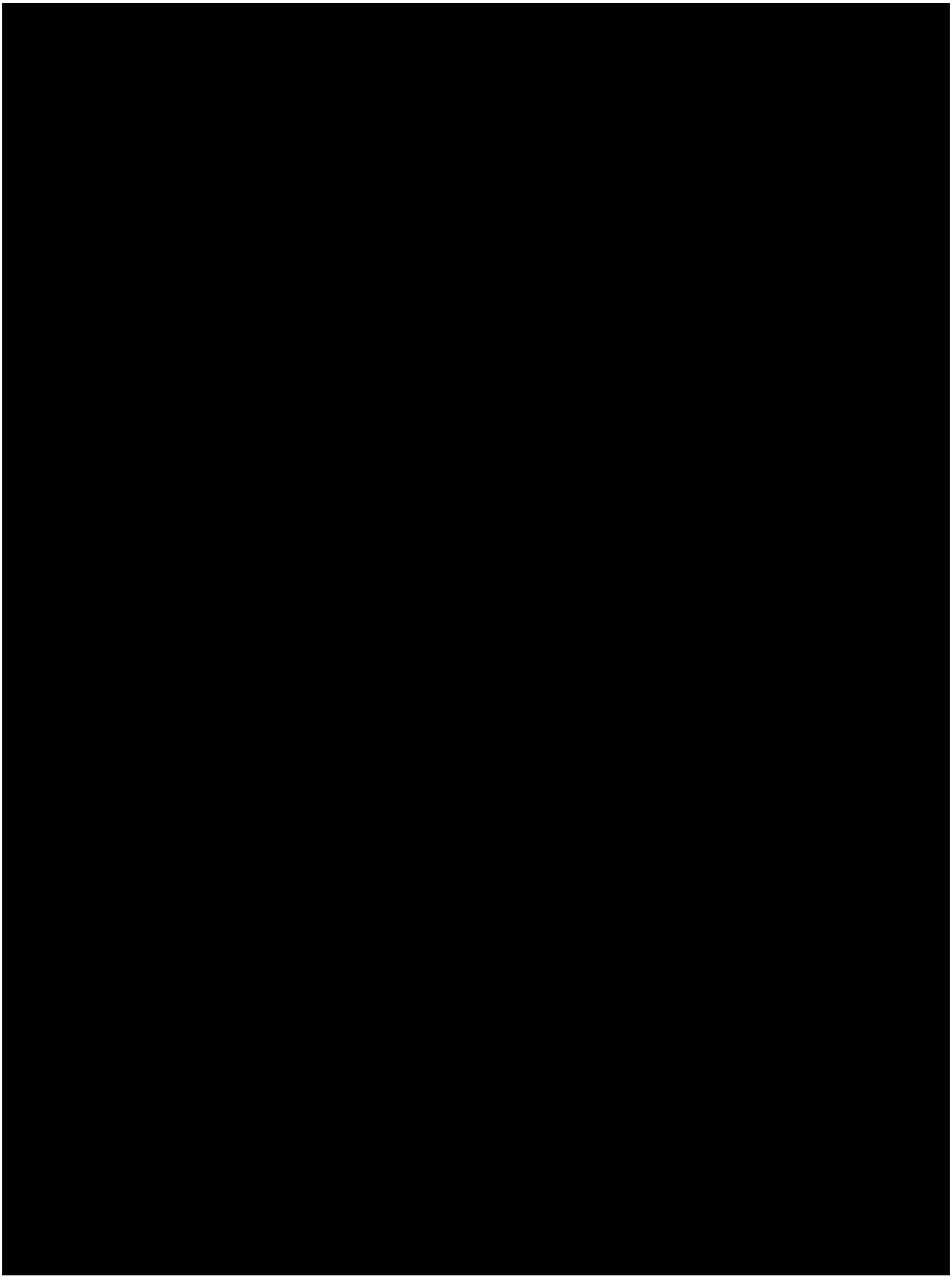
Kindyl Boyer
Advocacy Director
Infusion Access Foundation
kindyl.boyer@infusionaccessfoundation.org

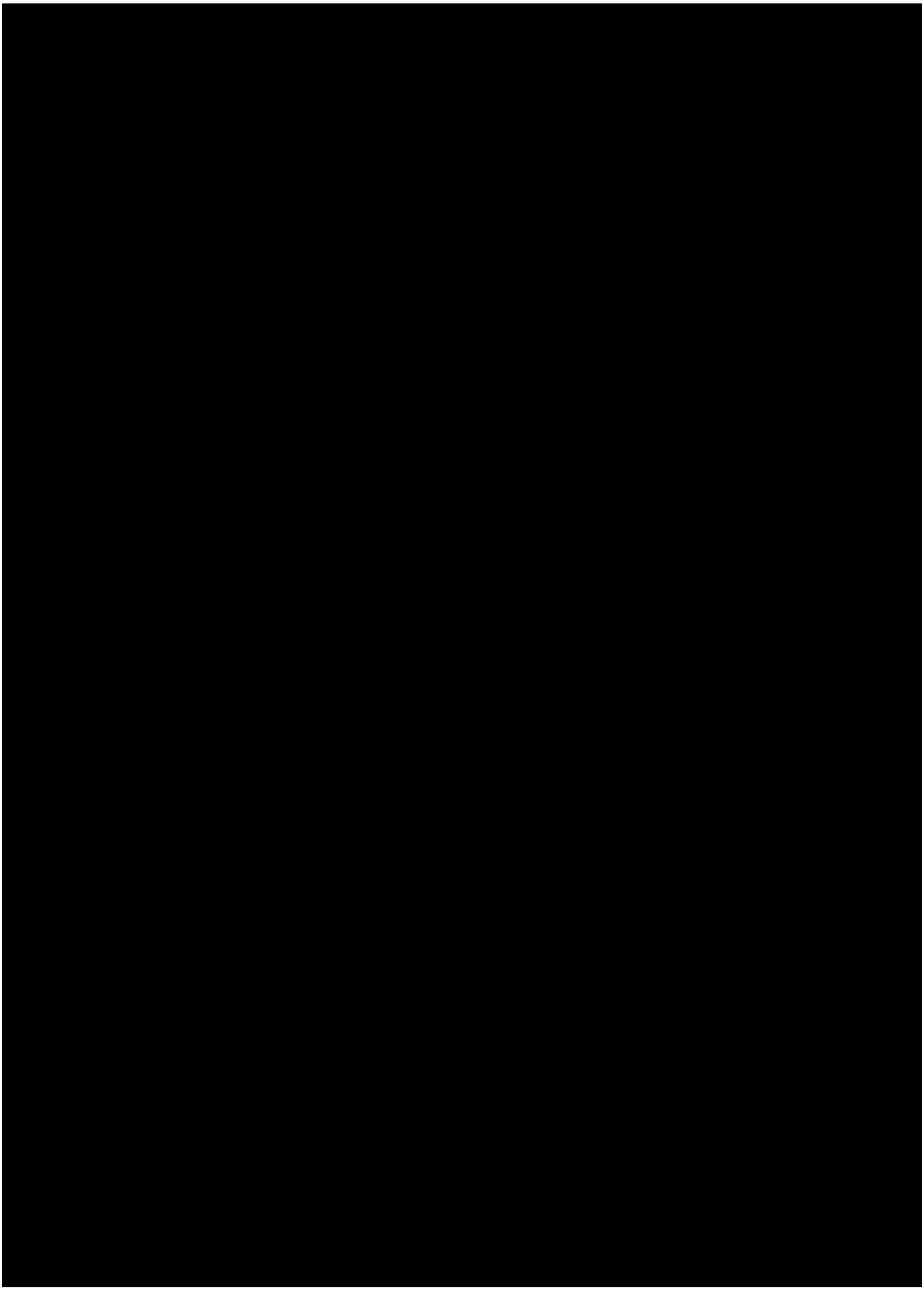
Laura Bonnell
CEO
The Bonnell Foundation:
Living with Cystic Fibrosis
thebonnellfoundation@gmail.com

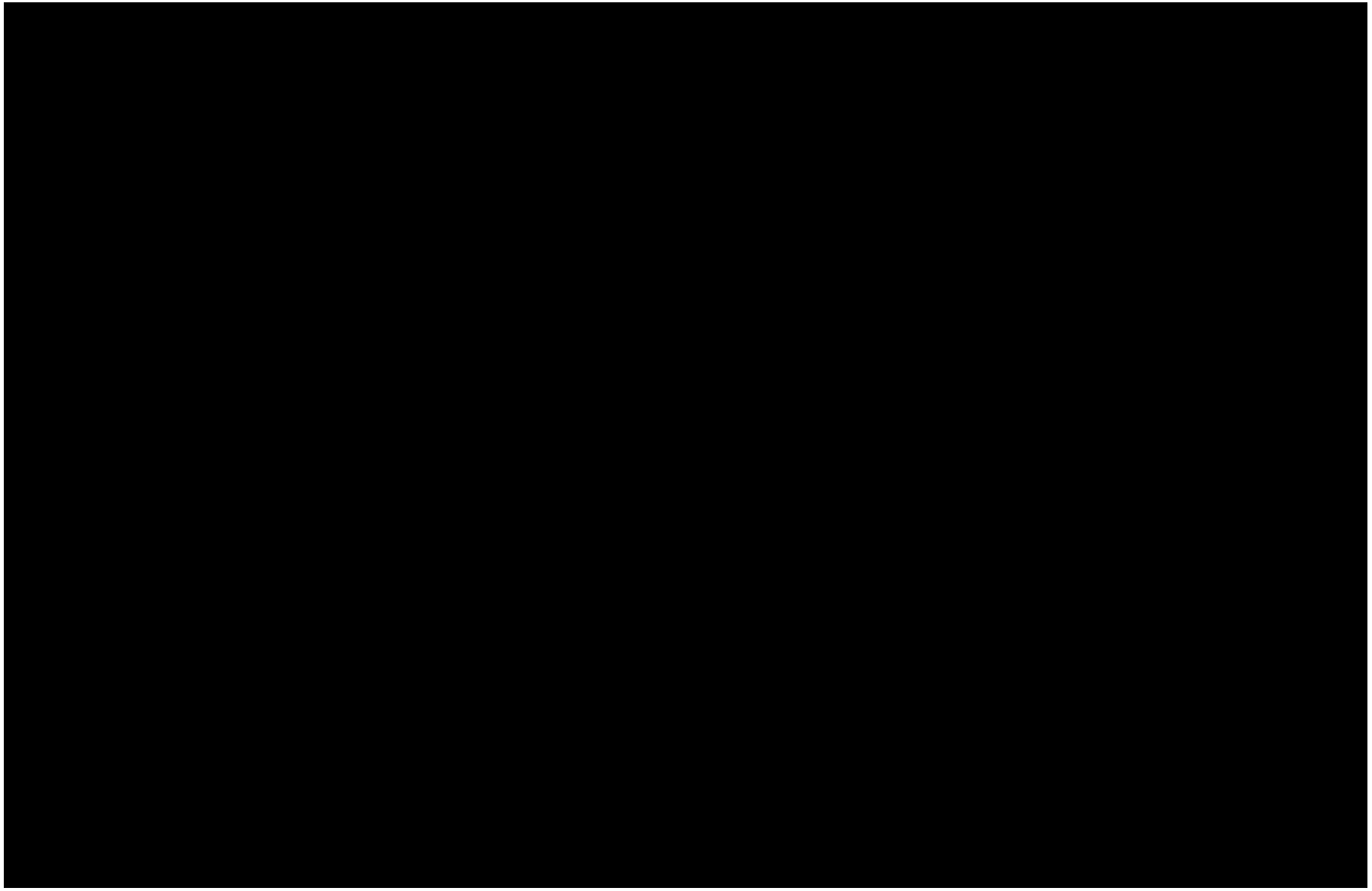
Novartis Services, Inc.
801 Pennsylvania Avenue NW
Suite 700
Washington, DC 20004

Courtney Piron
US Country President
Head, US Public Affairs
Telephone +1 202-253-1803









Appendix K

Cosentyx: Rebates, Discounts, and Price Concessions

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: To the extent practicable, the Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives.

The Board may consider manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities. (3 CCR 702-9, Part 3.1.E.2.j.i).

Policy: To the extent the Board has funding, information may be prepared from an external database regarding estimated manufacturer net sales and net costs (including rebates, discounts, and price concessions) for the prescription drug under review and, to the extent practicable, for therapeutic alternatives under review. Staff may also prepare information regarding manufacturer coupons to pharmacies and/or consumers. (PDAB Policy 04, p. 8).

Underlying Methodology: Board staff compiled data for the selected prescription drug for the Board's consideration in the following manner:

- Board staff contracted with SSR Health[1] to receive their proprietary U.S. prescription brand drug pricing and analytics database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net-sales and gross-to-net estimates quarterly for all drugs.[2] The gross-to-net estimates provide a quarterly estimated gross-to-net percent that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.
- Board staff gathered these estimates for Cosentyx, which are presented below. The estimates are on a rolling four quarter basis.
- Board staff used publicly available information on patient assistance programs to identify manufacturer coupons and discount programs available to patients.

Data Source(s): Board staff compiled information on rebates, discounts, and price concessions for Cosentyx from the following sources:

- SSR Health for estimated gross-to-net sales,
- Results of public input sessions and surveys for patients and caregivers, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations:

- SSR Health data is proprietary and confidential. Estimates are national and do not necessarily reflect rebates, discounts, and price concessions in Colorado

[1] SSR Health: https://www.ssrhealth.com/

[2] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

- Publicly available patient assistance program information is limited and does not reflect the number of patients who qualify and regularly receive assistance and the process for patients to receive assistance.

Cosentyx: Rebates, Discounts, and Price Concessions Evidence

Background

This appendix includes information on gross-to-net estimates, net-sales estimates, and manufacturer financial assistance programs information. For the purposes of this appendix, these terms mean:

- Gross-to-net Sales Estimate means the proprietary estimate as a percentage where SSR Health estimates all price concessions the manufacturer gives, including rebates, 340B discounts, and coupons provided by manufactures compared to gross sales to get a percentage estimate of all discounts. All gross-to-net sales estimates are provided on a four quarter moving average to provide full annual estimates and smooth quarter to quarter variation.
- Net-sales Estimate means the proprietary estimate of net sales based on sales information from 10-K financial reports and other publically available sources including earnings calls, press releases, and investor presentations.[3]
- Manufacturer financial assistance program estimate - This is different from the broader “patient assistance program” or “assistance program” terminology used in the Summary Report and in other appendices. While those later terms cover any patient assistance programs, information in this summary just pertains to financial assistance programs offered by the prescription drug manufacturer.

Information for gross-to-net estimates and net-sales estimates is provided first, followed by manufacturer financial assistance programs.

[3] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data

SSR Health Estimates

Figure K-1
Cosentyx Net-Sales and Gross-to-Net Estimates

Figure K-1 shows the net sales and gross-to-net estimates for Cosentyx since it first launched in 2016. The total gross-to-net estimate in January 2016 was [redacted], which increased to [redacted] in the fourth quarter of 2023.

Table K-1
Estimated Gross-to-Net for the Fourth Quarter of 2023

Gross-to-Net Measure	Cosentyx	Skyrizi	Stelara	Taltz	Tremfya
Total	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total less Statutory Medicaid	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table K-1 shows the gross-to-net estimates broken out by total (all), statutory Medicaid (reflect most Medicaid rebates, but not all such as best price), and total less statutory Medicaid (commercial and Medicare Part D plans). The statutory Medicaid estimate is likely derived from the base 23.1% rebate required under statute[4] and not the Medicaid best price requirement that generates greater discounts. This means that the Medicaid discounts for Cosentyx should actually exceed those provided to non-Medicaid entities.

Figure K-2
Estimated Total Gross-to-Net Sales

[4] 42 CFR § 447.509 Medicaid drug rebates (MDR)

Figure K-2 shows the total gross-to-net sales estimate for Cosentyx and identified therapeutic alternatives. The gross-to-net estimate for Cosentyx has increased to [redacted] in the fourth quarter of 2023, [redacted]

Table K-2

Gross-to-Net Estimate (Cosentyx and Therapeutic Alternatives)

Quarter Date	Cosentyx	Siliq	Skyrizi	Stelara	Taltz	Tremfya
January 2016	[redacted]			[redacted]		
April 2016	[redacted]			[redacted]	[redacted]	
July 2016	[redacted]			[redacted]	[redacted]	
October 2016	[redacted]			[redacted]	[redacted]	
January 2017	[redacted]			[redacted]	[redacted]	
April 2017	[redacted]			[redacted]	[redacted]	
July 2017	[redacted]			[redacted]	[redacted]	[redacted]
October 2017	[redacted]			[redacted]	[redacted]	[redacted]
January 2018	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
April 2018	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
July 2018	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
October 2018	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
January 2019	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
April 2019	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
July 2019	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
October 2019	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
January 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2020	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2021	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Quarter Date	Cosentyx	Siliq	Skyrizi	Stelara	Taltz	Tremfya
April 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
July 2022	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October 2022	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
January 2023	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
April 2023	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
July 2023	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
October 2023	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]

Table K-2 lists the quarterly gross-to-net estimates from January 2016 to October 2023 for Cosentyx and identified therapeutic alternatives. If a cell is left empty, there were no estimates for that drug during that quarter.

Figure K-3

Cosentyx Net-Sales Estimate as a percent of Novartis' Total Net-Sales Estimate

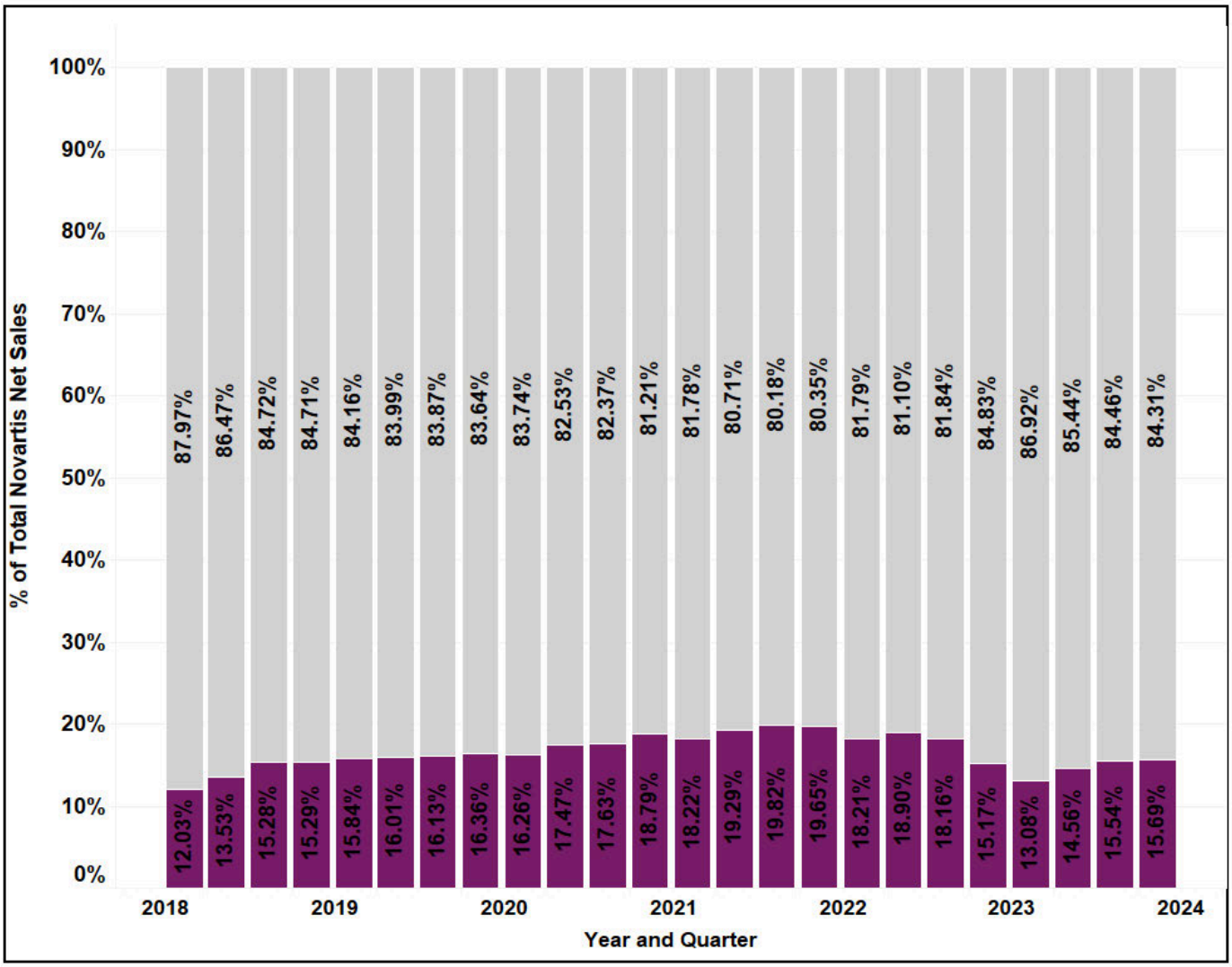


Figure K-3 shows Cosentyx net sales estimates (in purple) as a percent of Novartis' total net sales from the first quarter of 2016 through the fourth quarter of 2023. In the fourth quarter of 2023, Cosentyx accounted for an estimated [redacted] of Novartis' total net sales. Additional information of manufacturer-reported information of Cosentyx's share of Novartis' total sales is contained in Appendix O.[6]

Table K-3

Quarterly Net-Sales Estimate

Year	Quarter	Cosentyx	Siliq	Skyrizi	Stelara	Taltz	Tremfya
2016	Q1	[redacted]			[redacted]		
2016	Q2	[redacted]			[redacted]	[redacted]	
2016	Q3	[redacted]			[redacted]	[redacted]	
2016	Q4	[redacted]			[redacted]	[redacted]	
2017	Q1	[redacted]			[redacted]	[redacted]	
2017	Q2	[redacted]			[redacted]	[redacted]	
2017	Q3	[redacted]			[redacted]	[redacted]	[redacted]
2017	Q4	[redacted]			[redacted]	[redacted]	[redacted]
2018	Q1	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
2018	Q2	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
2018	Q3	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
2018	Q4	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
2019	Q1	[redacted]	[redacted]		[redacted]	[redacted]	[redacted]
2019	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2019	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2020	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q1	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2021	Q3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]000
2021	Q4	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[6] Appendix O contains information of Cosentys's net sales for national and international sales, whereas this appendix contains estimates for national sales only.

Year	Quarter	Cosentyx	Siliq	Skyrizi	Stelara	Taltz	Tremfya
2022	Q1	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
2022	Q2	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
2022	Q3	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
2022	Q4	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
2023	Q1	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
2023	Q2	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
2023	Q3	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
2023	Q4	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]

Table K-3 lists the quarterly estimates for the net-sales for Cosentyx and identified therapeutic alternatives from January 2016 to October 2023. These amounts are the same as reflected in Figure K-3 above.

Pursuant to section 10-16-1405(1)(a)(V-VII), C.R.S., each carrier and PBM must report the fifteen prescription drugs for which the carrier received the most frequent, the largest as a percent of spend on the drug, and the largest in dollars rebates. In 2021:

- 24% (6 of 25) of carriers indicated that Cosentyx was in the top 15 drugs for which the carrier received the largest rebate (one carrier ranked it first, one carrier ranked it third, one carrier ranked it eighth, one carrier ranked it eleventh, one carrier ranked it thirteenth, and one carrier ranked it fifteenth).
- One carrier indicated that Cosentyx was in the top fifteen prescription drugs for which the carrier received the highest rebate, as determined by the percentage of the price of the drug (ranking it 6th).

Figure K-4
Carrier's Rank of Cosentyx Rebates

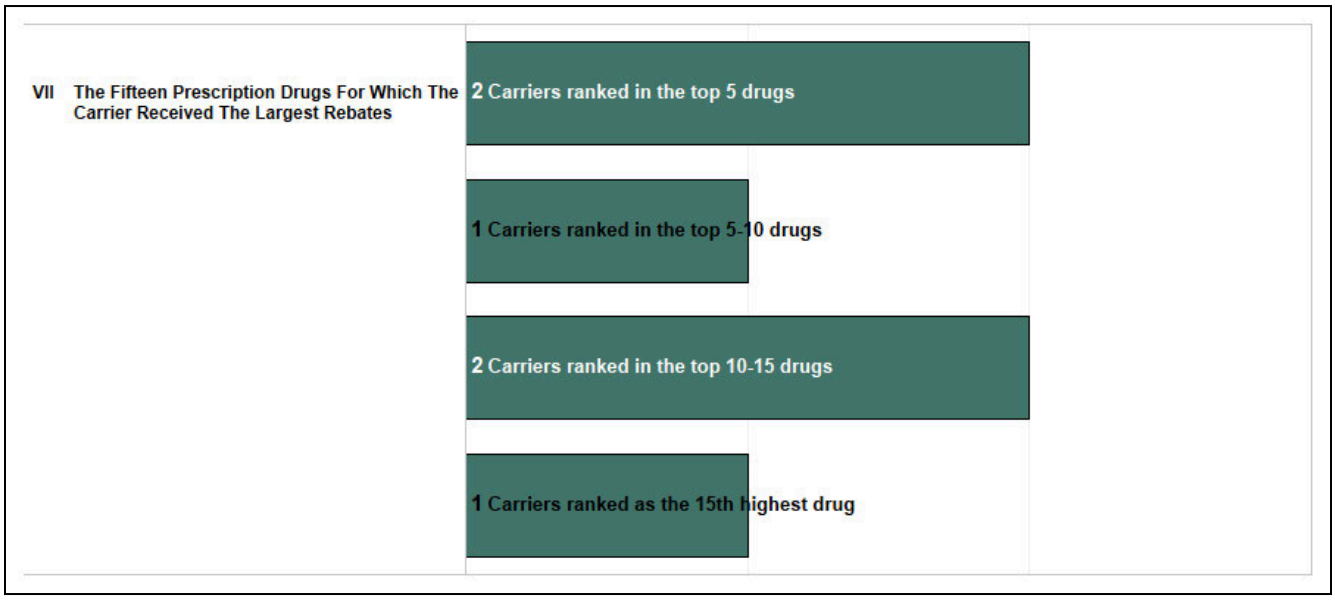


Figure K-4 shows the number of carriers who ranked Cosentyx in the top 15 rebated drugs for each rebate related reference.

Manufacturer Financial Assistance Programs

Novartis submitted the following statement regarding patient assistance programs: “In fact, the vast majority of patients who access Cosentyx through commercial health coverage pay nothing out-of-pocket due to the Novartis co-pay support program available to eligible Cosentyx patients. Many other moderate-income, lower-income, and underinsured patients pay nothing for Cosentyx via the Novartis Patient Assistance Foundation.”[7] Novartis also stated “The vast majority of patients, too, enjoy significant assistance even beyond the net price of Cosentyx and their insurance coverage through the Cosentyx Co-Pay Program or the charitable assistance of the Novartis Patient Assistance Foundation (NPAF). These programs further reduce the cost patients pay, often to as little as $0.”

The manufacturer also expanded on the Novartis Patient Assistance Foundation (NPAF) in their statement: “Further, for patients who are uninsured or under-insured (commercially-insured or in government-funded insurance programs), NPAF provides Novartis treatments at no cost to eligible U.S. patients who are experiencing financial hardship and have limited or no prescription drug coverage. NPAF is an independent, 501(c)(3) non-profit, non-commercial entity. Patients who cannot afford the cost of their Novartis medication may be eligible to receive it from NPAF at no cost. In 2021, NPAF provided more than $4 billion in free medicines to more than 127,000 patients in the U.S., covering 71 medicines from our portfolio. Over the last five years, through NPAF, medications valued at $13.5 billion have been made available to 445,000 patients at no cost.”

Board staff gathered further information on the manufacturer's financial assistance program, Cosentyx Connect,[8] via their public website. Cosentyx Connect is available to patients with private insurance and is not valid under Medicare, Medicaid, or any other federal or state healthcare program. Cosentyx Connect provides up to $16,000 annually for the cost of Cosentyx and up to $150 per infusion (up to $1,950 annually) for the cost of administration. The program is intended to be credited towards the patient’s out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles.

For patients with private insurance and whose prescription coverage is not initially approved, the Covered Until You’re Covered Program can provide Cosentyx at no cost to eligible patients for up to two years or until they receive insurance coverage approval, whichever occurs earlier.[9] Eligible patients must have private insurance, a valid prescription for Cosentyx, and a denial of insurance coverage based on a prior authorization request. The program requires the submission of an appeal of the coverage denial within the first 90 days of enrollment in order to remain eligible. Like Cosentyx Connect, this program is also not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program.[10]

Novartis submitted confidential and proprietary information regarding its assistance programs: [redacted]

Board staff heard from patients, caregivers, and individuals with scientific or medical training that patients utilize Cosentyx Connect to assist with the cost of Cosentyx. See Appendices H, I, and J for more information on both manufacturer financial assistance programs and other patient assistance programs.

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[7] https://drive.google.com/file/d/1OBlqpVr59SM04tYe8hHm5WOqf8dLutlZ/view?usp=drive_link

[8] https://www.cosentyx.com/all/treatment-cost

[9] https://www.cosentyx.com/all/treatment-cost

[10] https://www.cosentyx.com/all/treatment-cost

[redacted]

Appendix L

Cosentyx: Health Equity Factors

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule:The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations. (3 CCR 702-9, Part 3.1.E.2.j.ii).

Policy: Staff will prepare information regarding changes in utilization as compared to changes in WAC and changes in expenditures as identified in APCD data, attempting to understand changes in utilization by:

- People experiencing homelessness;
- People involved in the criminal justice system;
- Black people, indigenous people, and people of color;
- American Indians and Alaska natives;
- Veterans;
- People who are lesbian, gay, bisexual, transgender, queer, or questioning;
- People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth;
- People who have AIDs or HIV;
- Older adults;
- Children and families;
- People with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities;
- Other populations as deemed appropriate by the Prescription Drug Affordability Board. (PDAB Policy 04, pp. 8-9).

Underlying Methodology: Board staff have compiled data on health equity factors for the Board's consideration in the following manner:

1. Staff conducted an analysis into the Social Vulnerability Index (SVI) score of counties where individuals who used Cosentyx live.
2. Staff conducted a literature review to understand if the indications for the selected prescription drug disproportionately impact priority populations.

Data Sources: Board staff compiled information on health equity factors for the selected prescription drug from the following sources:

- The Social Vulnerability Index (SVI), created by the U.S. Center for Disease Control (CDC) Geospatial Research, Analysis and Services Program, which uses 16 U.S. census variables to determine the social vulnerability of counties. This program defines social vulnerability as factors, including poverty, lack of access to transportation, and crowded housing that may weaken a community's ability to prevent suffering and financial loss in a disaster.[1]
- APCD data to identify the county of residence of patients who took Cosentyx in 2022.
- Peer-reviewed journals pertaining to the indications treated by the selected prescription drugs and potential impacts on priority populations.

Considerations and Data Limitations: The SVI is calculated on a county basis, and does necessarily reflect the circumstances of the utilizers of the prescription drug. County of residence at the time each prescription was used, if individuals moved during 2022, their utilization factors into the percent of total patients from each county where they resided throughout the year.

[1] https://www.atsdr.cdc.gov/placeandhealth/svi/index.html

Cosentyx: Health Equity Factors Evidence

Social Vulnerability Index (SVI) Information

Board staff calculated SVI scores for patients who utilized Cosentyx in the following manner:

1. Staff used 2020 Social Vulnerability Index (SVI) data by county in Colorado and calculated the straight statewide average overall SVI score of 49.21%.
2. Counties with an SVI score higher than 49.21% were classified as higher than the statewide average, meaning that individuals residing in these counties may be more vulnerable to adverse outcomes due to social conditions in their county.
3. Counties with an SVI score lower than 49.21% were classified as lower than the statewide average, meaning that individuals residing in these counties may be less vulnerable to adverse outcomes due to social conditions in their county.
4. Staff aggregated APCD data based on the county of residence of utilizers of Cosentyx and calculated a percent of total patients who resided in each county in Colorado in 2022.
5. Staff combined these two data sources to determine the percent of patients who used Cosentyx in 2022 who resided in Colorado counties with SVI scores above the statewide average.

Following the methodology outlined above, staff calculated that 56.82% of patients who filled a prescription for Cosentyx lived in a county with an SVI score above the statewide average of 49.21%, meaning that 56.82% of Cosentyx patients lived in a county with higher social vulnerability. This could indicate that patients who utilize Cosentyx are located in counties that are more vulnerable to adverse outcomes due to social conditions in their county than patients in the average Colorado county.

Figure L-1

Map of Colorado by 2022 SVI Score for Utilizers of Cosentyx

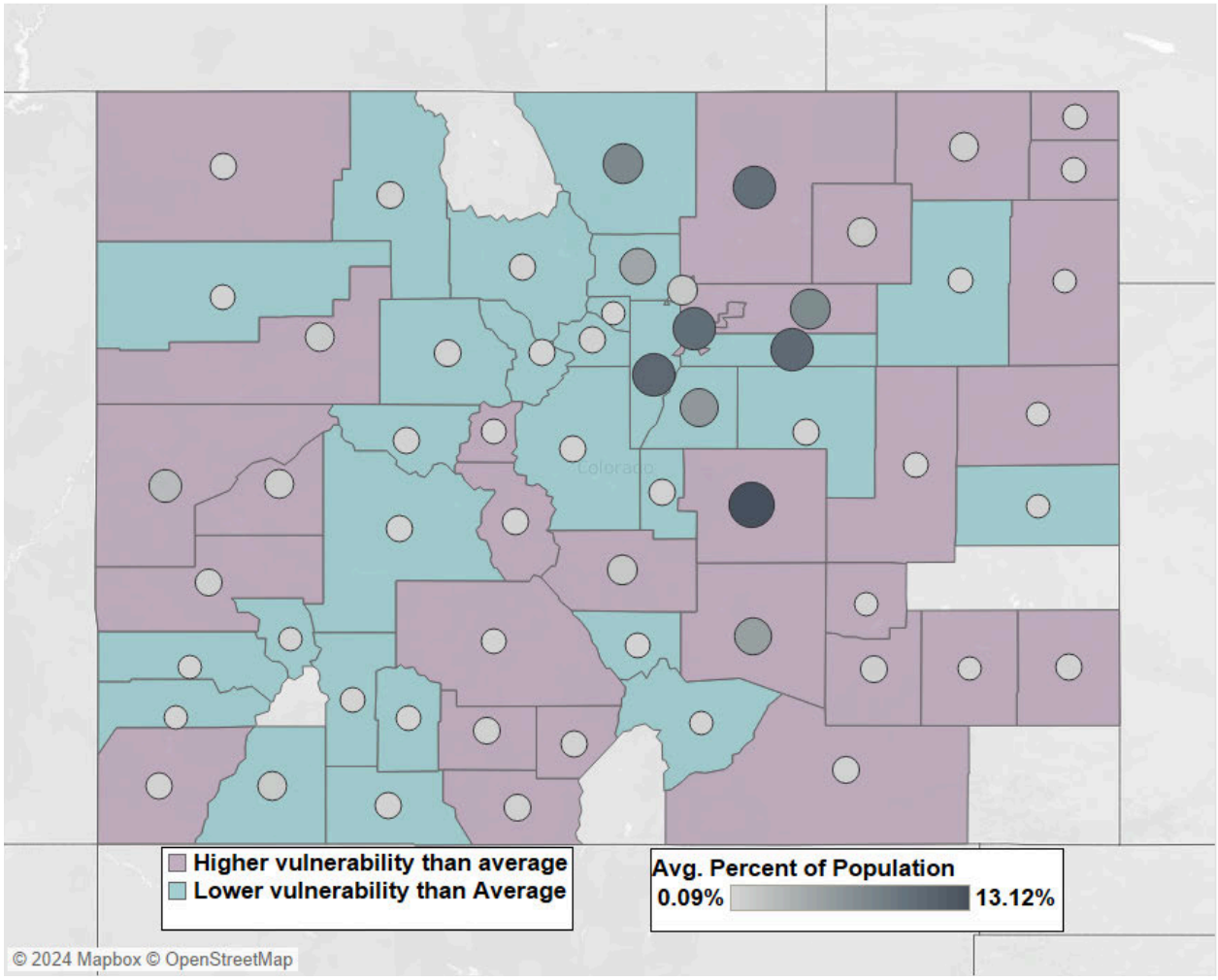

Figure L-1 shows the state of Colorado by county, where purple counties indicate higher than average SVI scores and teal counties indicate a lower than average SVI score, and counties without color did not have any patients who used Cosentyx in 2022 residing in them. The dots on each county show the percent of patients who used Cosentyx in 2022 by county where a larger, darker dot represents a higher portion of utilizers and smaller, lighter dots represent a smaller portion of the population.

Table L-1

Percent of Patients of Cosentyx and Therapeutic Alternatives by County

	County	County SVI Score	Cosentyx	Ilumya	Skyrizi	Stelara	Taltz	Tremfya
	ADAMS	80.95%	7.26%	6.45%	6.91%	6.22%	7.11%	6.52%
	ALAMOSA	100.00%	0.25%			0.31%	0.53%	0.22%
	BACA	52.38%				0.11%		
	BENT	82.54%	0.09%				0.18%	
	CHAFFEE	63.49%	0.18%		0.10%	0.35%	0.26%	0.22%
	CONEJOS	93.65%	0.42%			0.06%	0.09%	0.22%

Counties with Higher Vulnerability Than Average	CROWLEY	77.78%	0.09%		0.10%		0.26%	0.22%
	DELTA	79.37%	0.77%		0.39%	0.54%	0.70%	0.45%
	DENVER	73.02%	10.11%	12.90%	15.18%	13.02%	9.30%	9.89%
	EL PASO	53.97%	13.12%	6.45%	11.38%	10.84%	12.89%	15.28%
	FREMONT	60.32%	1.27%		0.29%	0.44%	0.96%	0.22%
	GARFIELD	61.90%	0.99%	3.23%	0.29%	0.69%	1.49%	1.12%
	KIT CARSON	69.84%				0.07%		0.22%
	LAKE	57.14%	0.12%			0.14%	0.35%	
	LAS ANIMAS	85.71%	0.37%		0.10%	0.24%	0.09%	0.45%
	LINCOLN	55.56%	0.14%					
	LOGAN	71.43%	0.68%		0.78%	0.50%	0.61%	0.45%
	MESA	74.60%	2.40%	32.26%	4.28%	3.80%	2.81%	0.45%
	MOFFAT	90.48%	0.35%		0.10%	0.22%	0.09%	0.67%
	MONTEZUMA	58.73%	0.22%		0.19%	0.24%	0.61%	0.22%
	MONTROSE	68.25%	0.53%		0.19%	0.55%	0.26%	0.67%
	MORGAN	92.06%	0.95%		0.39%	0.29%	1.14%	1.35%
	OTERO	87.30%	0.51%		0.49%	0.12%	0.35%	0.45%
	PHILLIPS	50.79%	0.10%			0.21%	0.09%	
	PROWERS	98.41%	0.20%		0.19%	0.11%	0.26%	
	PUEBLO	84.13%	5.10%	3.23%	1.95%	2.48%	2.72%	4.04%
	RIO GRANDE	96.83%	0.37%		0.19%	0.34%	0.44%	
	SAGUACHE	88.89%	0.10%			0.06%		
	SEDGWICK	76.19%	0.10%		0.10%		0.18%	
	WELD	66.67%	9.98%	16.13%	7.88%	5.73%	10.79%	12.13%
	YUMA	65.08%	0.09%			0.15%	0.26%	0.45%
	Total		***56.82%***	***80.56%***	***51.47%***	***47.82%***	***54.82%***	***55.91%***
	ARAPAHOE	49.21%	10.49%	12.90%	10.41%	12.70%	8.86%	8.54%
	ARCHULETA	41.27%	0.22%			0.12%	0.18%	
	BOULDER	39.68%	4.43%	3.23%	5.06%	6.20%	4.47%	4.04%
	BROOMFIELD	9.52%	1.27%		2.24%	1.34%	1.05%	1.12%
	CHEYENNE	14.29%			0.10%	0.14%		

Counties with Lower Vulnerability Than Average	CLEAR CREEK	19.05%	0.31%		0.10%	0.10%	0.18%	
	CUSTER	6.35%	0.14%			0.06%	0.09%	0.22%
	DOLORES	12.70%			0.10%			
	DOUGLAS	1.59%	5.81%		9.05%	8.34%	6.05%	6.52%
	EAGLE	44.44%	0.36%		0.58%	1.07%	0.61%	0.90%
	ELBERT	0.00%	0.26%		0.49%	0.44%	0.35%	0.90%
	GILPIN	4.76%			0.10%		0.09%	
	GRAND	28.57%	0.24%			0.27%		0.22%
	GUNNISON	25.40%	0.18%		0.10%	0.30%	0.44%	0.22%
	HINSDALE	38.10%	0.14%					0.22%
	HUERFANO	42.86%			0.10%	0.15%	0.09%	
	JEFFERSON	20.63%	10.75%	3.23%	10.99%	11.78%	9.21%	9.44%
	LA PLATA	36.51%	1.00%		0.78%	0.65%	0.88%	
	LARIMER	33.33%	7.47%	3.23%	7.00%	6.32%	8.68%	9.44%
	MINERAL	22.22%	0.10%			0.06%	0.09%	
	OURAY	6.35%	0.09%			0.11%	0.18%	
	PARK	3.17%	0.20%		0.29%	0.38%	0.26%	
	PITKIN	15.87%	0.26%		0.19%	0.35%	0.35%	
	RIO BLANCO	47.62%	0.15%			0.17%	0.26%	0.22%
	ROUTT	11.11%	0.42%		0.49%	0.56%	0.26%	1.80%
	SAN MIGUEL	26.98%	0.09%		0.10%	0.26%	0.18%	0.22%
	SUMMIT	30.16%	0.18%		0.49%	0.46%	0.96%	0.22%
	TELLER	17.46%	0.33%		0.10%	0.34%	0.88%	0.22%
	WASHINGTON	34.92%	0.15%		0.10%	0.07%		
	Total		***45.02%***	***22.59%***	***48.96%***	***52.71%***	***44.65%***	***44.46%***

Table L-1 shows a breakdown of the SVI score of each county, with higher than average vulnerability counties listed first, with the percent of utilizers in each county for Cosentyx and identified therapeutic alternatives in 2022. Please note the percent of utilizers may not equal 100% as some patients may have moved throughout the year and might be counted in each location where they lived while filling a prescription.

Figure L-2
SVI Score for Cosentyx and Therapeutic Alternatives

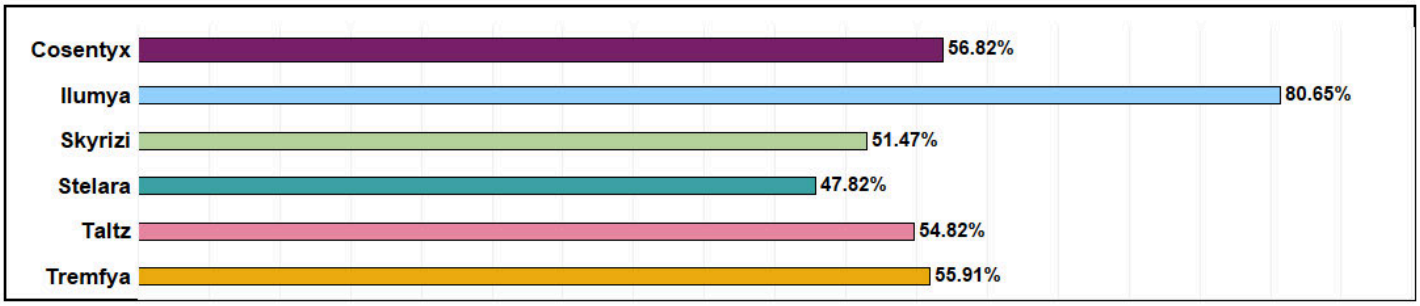

Figure L-2 shows the percent of utilizers of Cosentyx and identified therapeutic alternatives that lived in a county with a higher social vulnerability index score than the statewide average.

Health Equity Literature Review

Literature reviews were conducted for each of Cosentyx's FDA-approved indications and are meant to provide a broad overview of potential health equity impacts related to the disease or condition. Citations are provided for more information regarding the specific study populations, locations, timeframes, and categories or subcategories of the indication being studied.

Plaque psoriasis (PsO)

Psoriasis is an immune-mediated disease that affects 3.0% of the U.S. adult population, or more than 7.5 million adults. Plaque psoriasis is the most common subtype of psoriasis, affecting up to 80 percent of those with psoriasis.[2] Psoriasis has higher prevalence among white individuals (3.6%) compared with Asian (2.5%), Hispanic (1.9%), and Black (1.5%) individuals.[3]

Lack of culturally competent care was identified as a key unmet need for psoriasis among people with skin of color. One study reported that Hispanic and Black patients with psoriasis experienced more provider-related bias, stereotyping, misdiagnosis, and delayed diagnosis compared with white patients. The clinical presentation of psoriasis is different in people with darker skin tones compared to those with lighter skin tones and contributes to delayed diagnosis in historically marginalized populations. Additionally, people with skin of color are underrepresented in clinical trials of psoriasis therapies.[4]

Compared with white patients with psoriasis, individuals with skin of color may be less familiar with and have different rates of treatment with biologic therapies for psoriasis, are more likely to be hospitalized for psoriasis, and their access to physicians may differ. One study demonstrated significantly higher odds of hospitalization for psoriasis among Black, Hispanic, and Asian individuals. The same study also found higher rates of hospitalization for psoriasis among Medicare and Medicaid recipients, and uninsured patients compared with privately insured patients.[5] Black patients were less likely to receive biologic treatment or effective medications for their psoriasis compared with white patients. One study found that 8.3% of Black patients received a disease-modifying antirheumatic drug (DMARD) for their psoriasis, and 28% received a biologic therapy. In comparison, 13.3% of White individuals received a DMARD and 46.2% received a biologic therapy for their psoriasis. Additionally, patients of color reported high costs of care as a significant barrier to seeking and receiving treatment. Black, Asian, and other non-Hispanic historically marginalized populations are approximately 40% less likely to see a dermatologist for psoriasis compared with white patients.[6]

[2] https://www.psoriasis.org/locations-and-types/
[3] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[4] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[5] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub
[6] https://www.sciencedirect.com/science/article/abs/pii/S0733863522000961?via%3Dihub

Nearly one-third of psoriasis patients are in the pediatric age group. With an annual prevalence of up to 0.71%, childhood psoriasis can be regarded as a frequently seen chronic inflammatory skin disorder having a significant impact on the quality of life. Incidence of pediatric psoriasis varies between different ethnic groups, being highest in white and Black children. International studies have shown that pediatric psoriasis is more common in girls than in boys, but the difference is not always significant.[7]

Children with psoriasis require treatment until adulthood, and prolonged treatment may increase the risk of complications and adverse events, therefore it is crucial to adopt an effective treatment approach that reduces this risk. Long-term comorbidities associated with psoriasis may place a great burden on the physical and mental health of children with psoriasis beyond the effects of psoriasis itself. Pediatric patients with moderate-to-severe plaque psoriasis demonstrated significantly impaired health-related quality of life in relation to physical, emotional, social, and school functioning compared with healthy children, and pediatric psoriasis was associated with significantly worse quality of life than other skin diseases. Children with psoriasis are at approximately 20% to –30% higher risk of developing psychiatric disorders, such as depression and anxiety, than children without any psoriasis diagnosis. Anxiety or depression may stem from experiences of shame, behavior avoidance, bullying, decreased self-confidence, and social isolation caused by psoriasis.[8]

Psoriatic arthritis (PsA)

Often, patients with psoriasis are also diagnosed with psoriatic arthritis (PsA). Up to 30% of psoriasis patients initially present with a skin condition and then eventually progress into joint pain over 10 years following the initial psoriasis diagnosis.[9] The condition typically begins between the ages of 30 and 50, but children with psoriasis may also develop psoriatic arthritis. Though all races can get psoriasis and psoriatic arthritis, it is diagnosed more often in white people than people of other races and ethnicities.[10] One study found that white patients were five times more likely to be diagnosed with psoriatic arthritis compared with Black patients.[11] The disparity in prevalence could potentially be due to underdiagnosis in historically marginalized racial/ethnic groups.[12]

Though psoriatic arthritis is less frequent in Black patients compared to white patients, Black patients had more severe skin involvement, and greater psychological impact and impaired quality of life. One study reported a significantly higher degree of disease severity and lower use of biologics among Black patients compared with white patients.[13] One study found Black patients were 70% less likely to receive biologics than white patients.[14]

Insurance coverage may also impact diagnosis and treatment for psoriatic arthritis. One study found that Medicaid patients were less likely to be diagnosed with psoriatic arthritis, and only 12% of those with Medicaid saw a doctor who specializes in treating arthritis, compared to more than 50% of patients with other types of insurance. Those with private insurance or Medicare were more likely to get a correct diagnosis, see a specialist, and have targeted treatments.[15]

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[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683294/

[8] https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.17049#:~:text=International%20studies%20have%20shown%20that,significantly%20higher%20incidence%20in%20men.

[9] https://link.springer.com/article/10.1007/s40744-023-00580-y

[10] https://www.webmd.com/arthritis/psoriatic-arthritis/disparities-psoriatic-arthritis-diagnosis-treatment

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/

[12] https://link.springer.com/article/10.1007/s40744-023-00580-y

[13] https://link.springer.com/article/10.1007/s10067-014-2763-3

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9045033/#:~:text=Another%20study%20found%20that%20Black,worse%20disease%20severity%20%5B10%5D

[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/

Juvenile Idiopathic Arthritis (JIA) Subsets:
Juvenile Psoriatic Arthritis (JPsA) and Enthesitis-Related Arthritis (ERA)

Juvenile idiopathic arthritis (JIA) is an umbrella-term describing a group of conditions characterized by chronic arthritis beginning before the age of 16 years, persisting for at least 6 weeks, and having no other identifiable cause.[16] Juvenile Psoriatic Arthritis (JPsA) and Enthesitis-Related Arthritis (ERA) are included among the seven JIA subtypes outlined by the International League of Associations for Rheumatology (ILAR) classification for JIA.[17]

The disease burden of JIA is substantial as patients require specialized medical practitioners for diagnosis and chronic treatments that are both costly and time intensive. Discrepancies in access to care due to health inequities such as socioeconomic status or geographic location may lead to vastly different health outcomes.[18] Studies in the U.S. have shown that within the first year of diagnosis, children of color and those with lower household income have higher disease activity as well as a longer "time to first appointment"[19] Furthermore, previous studies have also shown that there is a notable economic burden of having a child with JIA due to costly medications and specialist treatments such as physiotherapy. [20]

Juvenile psoriatic arthritis (JPsA) affects 1-7% of children with JIA.[21] JPsA and its definition has been a matter of debate among pediatric rheumatologists for many years. The few studies that have compared the clinical characteristics and genetic determinants of JPsA with those of the other JIA categories have obtained contrasting findings. The debate on the categorization of JPsA as a distinct entity within JIA classification is still ongoing and has prompted the revision of its current classification.[22]

No research on health equity and JPsA is currently available.

Enthesitis-related arthritis (ERA) represents 5–30% of all cases of juvenile idiopathic arthritis (JIA) and belongs to the spectrum of the disorders included in the group of juvenile spondyloarthritis.[23] A multi-ethnic study from Canada revealed that patients with Asian origin have a higher prevalence of ERA compared to children with European or other non-European descent - the reasons for these findings are not clear but may be related to different genetics, epigenetics, or environmental risk factors.[24] The mean age at diagnosis is 10–13 years, and ERA is more prevalent in boys, as opposed to what is observed in JIA overall.[25]

Axial Spondyloarthritis Subsets:
Ankylosing spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

Axial spondyloarthritis (axSpA) is a chronic, inflammatory condition consisting of two subsets: ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA). AS is diagnosed through clinical findings and sacroiliac joint X-ray, and nr-axSpA is diagnosed based on clinical grounds and a normal x-ray with or without evidence of sacroiliitis on MRI.[26]

Historically, AxSpA has been thought to be more common in males than females by a ratio of 2–3:1, however this ratio is now known to be approximately 1:1.[27] Although recognition of axSpA in female patients has increased, women are still under-diagnosed, have higher disease activity, and reduced quality of life relative

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[16] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[17] https://ped-rheum.biomedcentral.com/articles/10.1186/s12969-021-00629-8
[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10629131/
[19] https://link.springer.com/article/10.1186/s12969-022-00676-9
[20] https://onlinelibrary.wiley.com/doi/abs/10.1002/art.22463
[21] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9821505/
[22] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9821505/
[23] https://www.mdpi.com/2227-9067/10/10/1647
[24] https://www.mdpi.com/2227-9067/10/10/1647
[25] https://www.mdpi.com/2227-9067/10/10/1647
[26] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8667771/
[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8667771/

to men.[28] On average, women wait about 8 years for an AS diagnosis while men wait about 6 years, and women may have more active disease because of a delay in diagnosis. In addition, men are more likely to receive a correct first diagnosis of AS (30%) compared with women (11%).[29] Many factors are thought to contribute to these disparities, including persistent clinician bias about axSpA being predominantly a male disease and poor communication between providers, resulting in a lack of awareness of potential gender differences in disease manifestation, leading to misdiagnosis.[30]

Studies have found that white individuals are more often diagnosed with ankylosing spondylitis when compared with Black and Hispanic individuals.[31] Researchers have raised concerns about detection bias with regard to diagnosing AS among people of color - since it has been believed that white people are at higher risk for AS, health care providers may tend to suspect AS more often when treating white patients while missing symptoms of spondylitis in patients of color.[32] Some researchers have noted that reduced access to diagnostic tests and specialists may also affect the numbers of people of color diagnosed with rheumatic diseases.[33]

Despite being diagnosed at lower rates than white and Hispanic patients, Black patients reported greater discomfort and impairment, had higher levels of inflammation, and showed more joint damage and deterioration on X-rays and MRIs.[34] A study in the Journal of Rheumatology found that Black patients with AS have both higher disease activity and comorbidities compared to white patients.[35] This is further complicated by the fact that people of color are underrepresented in clinical trials for inflammatory arthritis and genetic research as a whole.[36] As with many other inflammatory diseases, research suggests Black patients are not offered biologics as early on as white patients.[37] One study found that Black patients tended to undergo less treatment with biologic agents, despite having more severe disease.[38]

Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a debilitating and profoundly stigmatized chronic inflammatory skin disorder.[39] While HS can affect individuals of any racial or ethnic background, there is a clear racial bias in its prevalence, with people of color, particularly Black Americans, experiencing a significantly higher burden of the disease.[40] A retrospective study revealed a threefold higher prevalence of HS among Black individuals compared to white individuals.[41] Several independent studies have also shown that Black and Hispanic patients often exhibit a more severe manifestation of the disease compared to white patients.[42]

The disproportionate burden of HS among people of color extends beyond prevalence and severity - disparities can be observed in various aspects of the disease, including diagnostic delay and access to specialized care.[43] Research shows that Black and Hispanic patients experience a considerable delay in receiving a diagnosis, with an extended timeline of 1.6 and 1.5 years, respectively, compared to white

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[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8667771/
[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9568456/
[30] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9568456/
[31] https://www.jrheum.org/content/jrheum/47/6/835.full.pdf
[32] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8475338/
[33] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
[34] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
[35] https://www.jrheum.org/content/47/6/835.long
[36] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4082969/
[37] https://www.ajmc.com/view/black-patients-with-ra-less-likely-than-white-counterparts-to-be-prescribed-a-biologic
[38] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693696/
[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387178/
[40] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387178/
[41] https://jamanetwork.com/journals/jamadermatology/article-abstract/2626146
[42] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387178/
[43] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387178/#REF4

patients.[44] This delay in diagnosis has profound implications for the management of HS, as it leads to a prolonged period of untreated disease and further exacerbation of symptoms.[45]

Additionally, access to specialized dermatological care is crucial for effective HS management, and there are significant inequities in accessing such care, particularly for Black Americans. On average, Black Americans consult with a dermatologist around five years after the onset of HS, which is approximately two years later than their white and Hispanic American counterparts.[46] This delay in accessing dermatological care potentially worsens the disease condition and may contribute to the increased need for surgical intervention in advanced HS cases. In fact, a staggering 44.9% of Black Americans with HS were evaluated by a surgeon before a dermatologist, potentially underlining the substantial barrier in accessing timely dermatological care within this population[47]

Racial disparities in HS management also extend to clinical trials, where the underrepresentation of minority populations further limits understanding of the disease and its treatment efficacy. One study reviewed HS-specific clinical trials and found that out of 15 trials, only 14% of the included patients identified as Black Americans, while White Americans constituted a dominating 68%.[48] Similarly, another review similarly reported underrepresentation of Black, Hispanic or Latino, and American Indian or Alaska Native patients, constituting only 13.7%, 7.2%, and 1.3% of the trial population, respectively.[49]

While selected information has been pulled above, there is additional information contained in Appendix Appendix H: Input from Patients and Caregivers, Appendix I: Input from Individuals with Scientific and Medical Training, and Appendix J: Voluntarily Submitted Information which may contain additional information on health equity effects not captured in this appendix. The Board may want to weigh information from all four appendices when evaluating the health equity of Cosentyx.

[44] https://www.sciencedirect.com/science/article/pii/S0027968422001419
[45] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387178/#REF4
[46] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387178/
[47] https://www.sciencedirect.com/science/article/pii/S0027968422001419
[48] https://karger.com/drm/article-abstract/237/1/97/115008
[49] https://link.springer.com/article/10.1007/s00403-022-02510-4

Appendix M

Cosentyx: Information from the Department of Health Care Policy and Financing (HCPF)

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board shall consider information from HCPF as follows:

- Additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or
- Information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410. (3 CCR 702-9, Part 3.1.E.2.j.iii).

Policy: Staff will review any additional analyses conducted by HCPF relevant to the prescription drug or therapeutic alternative under review for presentation to the Board. (PDAB Policy 04, p. 9).

Underlying Methodology: None.

Data Source(s): Board staff sought to compile information for the selected prescription drugs from the following sources:

- Publicly available reports from the Colorado Department of Health Care Policy and Financing (HCPF).

Considerations and Data Limitations: If any selected prescription drugs or therapeutic alternatives were mentioned in public HCPF reports, Board staff planned to note any differences in definitions, the period of time being analyzed, or general characteristics of the prescription drugs or analytics being conducted.

Cosentyx: Information from the Department of Health Care Policy and Financing Evidence

Board staff requested any publicly available reports with quantitative or qualitative data related to Cosentyx from HCPF and were informed that there are no publicly available reports.

HCPF maintains a preferred drug list (PDL) with prior authorization requirements for self-administered drugs and Appendix P with prior authorization requirements for physician-administered drugs.[1] These lists are developed with recommendations from HCPF's Drug Utilization Review Board.[2]

HCPF's PDL outlines the following information effective as of April 1, 2024:[3]

- For ankylosing spondylitis (AS) (including non-radiographic axial spondyloarthritis (nr-axSpA)), psoriatic arthritis (PsA), plaque psoriasis (PsO), and other non-specified indications: Cosentyx is a non-preferred agent with prior authorization required.
- Of identified therapeutic alternatives:

[1] https://hcpf.colorado.gov/pharmacy-resources
[2] https://hcpf.colorado.gov/drug-utilization-review-board.
[3] https://hcpf.colorado.gov/sites/hcpf/files/04-01-24%20PDL%20V3.pdf

- For ankylosing spondylitis (AS) and nr-axSpA: Taltz is a preferred agent with no prior authorization required if diagnosis and eligibility criteria are met.
- For psoriatic arthritis (PsA): Taltz is a preferred agent with no prior authorization required if diagnosis and eligibility criteria are met, while Stelara, Skyrizi, and Tremfya are non-preferred agents with prior authorization required.
- For plaque psoriasis (PsO): Taltz is a preferred agent with no prior authorization required if diagnosis and eligibility criteria are met, while Stelara, Skyrizi, Siliq, and Tremfya are non-preferred agents with prior authorization required.

HCPF's Appendix P outlines the following information effective April 1, 2024:[4]

- Cosentyx IV injection may be approved if the following criteria are met:
  - For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
  - Request meets criteria listed for Cosentyx (secukinumab) on the Health First Colorado Preferred Drug List (PDL) for the requested FDA-approved indication.

Additionally, Board staff and HCPF discussed that there was no readily available list or email listserv of 340B covered entities that could be used to facilitate Board staff outreach.

[4] https://hcpf.colorado.gov/sites/hcpf/files/Appendix%20P%2004.01.24%20V2.pdf

Appendix N

Cosentyx: Non-Adherence and Utilization Management

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board shall consider any other factors as determined by rules promulgated by the board pursuant to section 10-16-1403(5). (C.R.S. § 10-16-1406(4)(j)).

Rule: The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. (3 CCR 702-9, 3.1.E.2.j.iv).

Policy: To the extent such information is available, the Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug. (PDAB Policy 04, p. 9).

Underlying Methodology: Board staff have compiled data for the selected prescription drug for the Board's consideration in the following manner:

1. Document information provided during the stakeholder sessions to gather input from patients and caregivers and individuals with scientific or medical expertise. Staff will attempt to compile information directly related to the information outlined in rule during stakeholder meetings, as well as a survey.
2. Relevant information provided by entities who submitted information voluntarily.

Data Source(s): Board staff compiled information on non-adherence and utilization management for Cosentyx from the following sources:

- Results of public input sessions and surveys by patients and caregivers and individuals with scientific and medical training, and
- Relevant voluntarily submitted information.

Considerations and Data Limitations: Input provided both via stakeholder meetings and surveys is voluntary. Such qualitative data may not capture information from all patients and caregivers.

Cosentyx: Non-Adherence and Utilization Management Evidence

See Appendix M for more information regarding the Department of Health Care Policy and Financing's (HCPF's) prior authorization requirements for Cosentyx and identified therapeutic alternatives. Additionally, six of ten carriers in the Colorado market cover Cosentyx. Three carriers that cover Cosentyx require prior authorization, two carriers require prior authorization and step therapy, and one carrier covers Cosentyx with unrestricted access. Please see Appendix E for more information.

Stakeholder Input

Through public input sessions and surveys, patients and caregivers disclosed information about non-adherence of Cosentyx due to cost. Of the five Colorado patients and caregivers surveyed:

- Four participants indicated that cost impacted their adherence to Cosentyx and three indicated they have changed prescription drugs in order to save money.
- Four participants said their insurance plan requires prior approval to fill the prescription, one worried that the cost of the prescription will raise their premium, and three said their insurance

requires them to try a medication that they previously failed or required them to use a drug that was not recommended by their doctor.

See Appendix H for more information.

Voluntarily Submitted Information

Novartis did not submit any information related to utilization management or adherence.

See Appendix J for more information.

Appendix O

Cosentyx: Pricing Information

Affordability Review Statute, Rule, and Policy Guidance

Statute: The Board may consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug. (C.R.S. § 10-16-1406(6)).

The Board may access pricing information through publicly available pricing information from state entities, the APCD, and other countries. (C.R.S. § 10-16-1406(7)(a)). Pricing information is defined as information about the price of a prescription drug, including information that explains or helps explain how the price was determined. (C.R.S. § 10-16-1401(20)).

To the extent that there is no publicly available information with which to conduct an affordability review, the Board may request that a manufacturer, carrier, or pharmacy benefit management firm provide pricing information for any prescription drug identified. (C.R.S. § 10-16-1406(7)(b)).

Rule: The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

- Life cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition;
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Board may access pricing information for prescription drugs by:

- Accessing publicly available pricing information from a state to which manufacturers report pricing information;
- Accessing available pricing information from the APCD and from state entities; and/or
- Accessing information that is available from other countries.

To the extent there is no publicly available information with which to conduct an affordability review, the Board may request that a manufacturer, carrier, or PBM provide pricing information for any prescription drug eligible for an affordability review.

- Such interested parties shall have 30 days from the date of the request of a prescription drug for affordability review to provide such information to the Board for its consideration.
- Failure of an entity to provide pricing information to the Board for an affordability review does not affect the authority of the Board to conduct the affordability review, as described in this section. (See 3 CCR 702-9, Parts 3.1.E.3, 4).

Policy: The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

- Life-cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition;
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Board may access pricing information for prescription drugs by:

- Accessing publicly available pricing information from a state to which manufacturers report pricing information. Staff will review other state programs and provide such information to the extent it is available.
- Accessing available pricing information from the APCD and from state entities.
- Staff will review pricing information in the APCD and, to the extent such data has not already been utilized in the affordability review, provide such information.
- Staff will review pricing information available from state entities and provide such information to the Board.
- Accessing information that is available from other countries. Staff will review pricing information from other countries and provide such information to the extent it is available. (PDAB Policy 04, pp. 9-10).

Underlying Methodology: None.

Data Sources: Board staff obtained pricing information through public reports and the following data sources:

- APCD data, including APCD data gathered pursuant to C.R.S. § 10-16-1405.
- Other state prescription drug transparency reports.
- U.S. Security and Exchange Commission (SEC) Form 10-K Filings.

Considerations and Data Limitations: Board staff did not recommend the Board specifically request pricing information from manufacturers, carriers, and PBMs since information is already both publicly available and available through the Division of Insurance's contract with AnalySource.[1] However, entities were able to choose to provide information related to the following components by submitting such information through the "Voluntarily Submitted Information" path by October 3, 2023:

- Life-cycle management;
- Average cost of the prescription drug in Colorado;
- Market competition
- Projected revenue;
- Estimated cost-effectiveness of the prescription drug; and/or
- Off-label usage of the prescription drug.

The Division of Insurance did not receive any voluntarily submitted information from entities with additional pricing information.

[1] AnalySource data contains information on Cosentyx's price - See Appendix A for more information.

Information accessed through searches for public reports and data may not always match exactly the type of data being compiled for other affordability review components. Board staff will note when publicly available data cannot be vetted for exact comparability.

Cosentyx: Pricing Information Evidence

Other State Transparency Reports

West Virginia

The West Virginia legislature passed Senate Bill 689 in 2020, requiring all pharmaceutical manufacturers that sell drugs directly or to wholesalers in West Virginia to submit pricing information to the State Auditor's Office for it to be visualized and transparent for the everyday consumer.[2] In 2023, this resulted in four published reports:

- Pharmaceutical Manufacturers WAC Report - Annual information from 2020 through 2022 is provided in a searchable database for both Cosentyx and Novartis, specifically introductory prices and weighted average costs for a singular strength and dosage form of Cosentyx as reported by the manufacturer in 2020 and 2022.
- Patent Exclusivity Report - Information regarding Novartis, but not Cosentyx, is contained in this report.
- WAC Increases - No information regarding Novartis, or Cosentyx, is contained in this report.
- Research and Development Costs - No Information regarding Novartis is contained in this report.

Minnesota

The Minnesota legislature passed a law creating the Prescription Drug Price Transparency Data and Dashboards.[3] In the Reporting Snapshot of data reported by June 2023, the Minnesota Department of Health (MDH) outlined 119 expected reports from Novartis Pharmaceuticals Corporation, with 61 reports received.[4] No information regarding Novartis, nor Cosentyx, was contained in the Price Increase - Five Year Price Analysis Dashboard or Comparative Price Change Analysis Dashboard.

The Price Increase - Five Year Price Analysis Dashboard[5] provided the following information regarding Cosentyx's price increases:

[2] https://stories.opengov.com/westvirginia/published/kFdN-WMxm.
[3] https://www.health.state.mn.us/data/rxtransparency/dashboards/index.html.
[4] https://www.health.state.mn.us/data/rxtransparency/dashboards/reporting.html.
[5] https://www.health.state.mn.us/data/rxtransparency/dashboards/fiveyear.html

Table O-1

Information from Minnesota

Manufacturer	NDC	Item Description	% Current Change	% Prior Year 1 Change	% Prior Year 2 Change	% Prior Year 3 Change	% Prior Year 4 Change	% Prior Year 5 Change	Prior Year 1 WAC	Prior Year 2 WAC	Prior Year 3 WAC	Prior Year 4 WAC	Prior Year 5 WAC	WAC After Current Change	WAC Effective Date
Novartis Pharmaceuticals Corporation	00078063968	Secukinumab 150 mg/ml solution Auto-injector 1.000 ml UD	2.00%	16.80%	0.00%	17.60%	6.50%	8.90%	$5,541	$5,541	$4,712	$4,425	$4,065	$6,471	7/27/2022
Novartis Pharmaceuticals Corporation	00078063997	Secukinumab 150 mg/ml Solution Prefilled Syringe 1.000 ml UD	2.00%	16.80%	0.00%	17.60%	6.50%	8.90%	$5,541	$5,541	$4,712	$4,425	$4,065	$6,471	7/27/2022
Novartis Pharmaceuticals Corporation	00078063998	Secukinumab 150 mg/ml Solution Prefilled Syringe 1.000 ml UD	2.00%	133.6%	0.00%	17.60%	6.50%	8.90%	$2,771	$2,771	$2,356	$2,212	$2,032	$6,471	7/27/2022

Table O-1 shows Minnesota's price transparency for five years of comparative price analysis for all evaluated Cosentyx NDCs.

The Price Increase - Comparative Price Change Analysis Dashboard[6] provided the following information regarding Cosetyx's price increases:

Table O-2

Information from Minnesota

Manufacturer	NDC	Item Description	$ Change 12 Month	% Change 12 Month	$ Change 24 Month	% Change 24 Month
Novartis Pharmaceuticals Corporation	00078063968	Secukinumab 150 MG/ML Solution Auto-injector 1.000 ML UD	$541.94	9.10%	$929.84	16.80%
Novartis Pharmaceuticals Corporation	00078063997	Secukinumab 150 MG/ML Solution Prefilled Syringe 1.000 ML UD	$541.94	9.10%	$929.84	16.80%
Novartis Pharmaceuticals Corporation	00078063998	Secukinumab 150 MG/ML Solution Prefilled Syringe 1.000 ML UD	$541.94	9.10%	$929.84	16.80%

Table O-2 shows Minnesota's price transparency comparative price analysis for evaluated Cosentyx NDCs.

[6] https://www.health.state.mn.us/data/rxtransparency/dashboards/comparative.html

Maine

The Maine legislature passed two laws related to prescription drug price transparency:

Public Law 2021, Chapter 606 (LD 1636)

This law requires the Maine Health Data Organization (MHDO) to produce an annual report beginning in 2023 that provides information regarding potential savings that could be achieved by subjecting drugs identified as the costliest and most frequently prescribed to a referenced rate as defined in law.[7]

Table O-3
Information from Maine

Potential Savings								
§8741 2. C. For each drug identified in paragraph A, the organization shall determine the potential savings that could be achieved by subjecting those drugs to the referenced rate as calculated pursuant to paragraph B. The savings must be determined based on the payments reported in the organization's claims database for the most current 12- month period.								
Top 100 List	**Manufacturer Name**	**NDC**	**Item Description**	**Average WAC Per Unit**	**Reference Rate**	**Annual Cost @ Average WAC Per Unit**	**Annual Cost @ Reference Rate Per Unit**	**Potential Savings**
Brand Most Costly	NOVARTIS	00078063941	Secukinumab 150 MG/ML Solution Auto-injector 1.000 ML UD	$3,422.4158	$3,422.4158	$7,248,271	$7,248,271	$0
Brand Most Costly	NOVARTIS	00078063968	Secukinumab 150 MG/ML Solution Auto-injector 1.000 ML UD	$6,844.8316	$6,844.8316	$2,544,064	$2,544,064	$0

Table O-3 shows the potential savings that could be achieved by subjecting Secukinumab 150 MG/ML Solution Auto-injector 1.000 ML UD to the referenced rate (determined based on payments reported in MHDO's claims database for the most current 12-month period) is $0.[8]

Public Law 2018, Chapter 406

This law requires MHDO to produce an annual prescription drug report that includes:

- The 25 costliest drugs (determined by total amount spent in the state),
- The 25 most frequently prescribed drugs in the state, and
- The 25 drugs with the highest year-over-year cost increase (determined by total amount spent in the state).[9]

[7] https://mhdo.maine.gov/RxReferenceRates.htm.
[8] Pulled from Part III of the International Referenced Rate Pricing for Prescription Drugs 2023 Report accessed via https://mhdo.maine.gov/RxReferenceRates.htm.
[9] https://mhdo.maine.gov/tableau/prescriptionReports.cshtml.

Information is provided for three state fiscal years, which run from July 1 through June 30. The most recent report is outlined below (July 1, 2021 through June 30, 2022):

Top 25 Costliest Drugs

- Overall: Cosentyx appears #16 on the list.
- Commercial: Cosentyx appears #9 on the list.
- Medicaid: Cosentyx appears #22 on the list.
- Medicare Advantage: Cosentyx does not appear on the list.

Figure O-1

Maine: Cosentyx Ranking Among Top 25 Costliest Drugs Overall

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				535,254	107,680	$757,322,271	
State Total				2,565,690	526,254	$2,327,906,117	
16	00078063941	Cosentyx Sensoready Pen	Disease-modifying Antirheumatic Drugs; Skin and Mucous Membrane Agents, Miscellaneous	2,356	369	$17,014,890	$7,222

Figure O-1 shows Cosentyx is the #16 costliest drug overall in 2021-2022.

Figure O-2

Maine: Cosentyx Ranking Among Top 25 Costliest Drugs for Commercial Plans

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				82,865	20,994	$287,743,460	
State Total				691,922	224,048	$667,145,150	
9	00078063941	Cosentyx Sensoready Pen	Disease-modifying Antirheumatic Drugs; Skin and Mucous Membrane Agents, Miscellaneous	1,126	180	$7,461,418	$6,626

Figure **O-**2 shows Cosentyx is the #9 costliest drug for commercial plans in 2021-2022.

Figure O-3

Maine: Cosentyx Ranking Among Top 25 Costliest Drugs for Medicaid

Rank	NDC	Drug Name	Drug Class(es)	Number of Prescriptions	Number of Prescription Users	Cost	Cost Per Prescription
Top 25 Overall				253,227	30,589	$151,049,958	
State Total				828,489	116,916	$407,109,334	
22	00078063941	Cosentyx Sensoready Pen	Disease-modifying Antirheumatic Drugs; Skin and Mucous Membrane Agents, Miscellaneous	409	62	$2,669,403	$6,527

Figure O-3 shows Cosentyx is the #22 costliest drugs for Medicaid in 2021-2022. Cosentyx does not appear on the list for top 25 costliest drugs for Medicare Advantage.

Top 25 Most Frequently Prescribed Drugs: Cosentyx does not appear on the list overall, nor specifically for commercial plans, Medicaid, or Medicare Advantage.

Top 25 Drugs with Highest Year-Over-Year Increases: Cosentyx does not appear on the list overall, nor specifically for commercial plans, Medicaid, or Medicare Advantage.

Oregon

The Oregon legislature created Oregon's Drug Price Transparency program in 2018 to provide accountability for prescription drug pricing through transparency of specific cost and price information from pharmaceutical manufacturers and health insurers.[10] Drug Price Transparency Program Reports are available from 2019-2023.[11] The 2023 report is outlined below.

The report identifies insurer reporting of the most costly drugs reflects the drugs with the highest total payments made on behalf of covered members, including payments made by carriers and member cost sharing, such as copays and coinsurance. Cosentyx appears #7 on the list (p. 61).[12]

[10] https://dfr.oregon.gov/drugtransparency/Pages/index.aspx.

[11] https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx.

[12] https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf

Figure O-4
Oregon: Top 10 Most Costly Drugs

Figure 31: Top 10 most costly drugs

Drug	Class	Total annual plan spending
Adalimumab Brand name: Humira	Analgesics/anti-inflammatory	$75,241,110
Ustekinumab Brand name: Stelara	Dermatologicals	$28,957,943
Pembrolizumab Brand name: Keytruda	Antineoplastics and adjunctive therapies	$28,248,898
Bictegravir-Emtricitabine-Tenofovir Alafenamide Fumarate Brand name: Biktarvy	Antivirals	$26,988,465
Etanercept Brand name: Enbrel	Analgesics/anti-inflammatory	$22,017,823
Elexacaftor-Tezacaftor-Ivacaftor Brand name: Trikafta	Respiratory agents	$21,559,651
Secukinumab Brand name: Cosentyx	Dermatologicals	$18,723,855
Vedolizumab Brand name: Entyvio	Gastrointestinal agent	$17,655,131
Infliximab-dyyb Brand name: Inflectra	Gastrointestinal agent	$16,516,923
Risankizumab-rzaa Brand name: Skyrizi	Dermatologicals	$15,517,811

Figure O-4 shows Cosentyx as #7 on the list of the top 10 most costly drugs in Oregon in 2023.

Information is also provided in this report regarding drugs with greatest increases in year-over-year health plan spending, as well as the amount of that increase. Cosentyx does not appear on the list (p. 62).[13]

[13] https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf

California

The California legislature passed two laws related to prescription drug price transparency:

Prescription Drugs Introduced to Market

This dataset provides data for new drugs introduced to market in California with a WAC that exceeds the Medicare Part D specialty drug cost threshold.[14] Prescription drug manufacturers submit information to the California Department of Health Care Access and Information (HCAI), including NDC, a narrative description of marketing and pricing plans, and WAC.

Prescription Drug WAC Increases

This dataset provides data for WAC increases that exceed the statutorily mandated WAC increase threshold of a 16 percent increase for the period including the current quarter and the previous two calendar years for prescription drug products with a WAC greater than $40 for a course of therapy.[15]

Texas

The Texas legislature passed House Bill 2536 in 2019, requiring pharmaceutical drug manufacturers to report the current WAC of drugs sold in or into Texas to the Texas Health and Human Services Commission (HHSC), as well as separately report specific information related to WAC increases.[16] Novartis reported WAC information on Cosentyx to HHSC in 2020, 2021, 2023, and 2024, reported other drugs but not Cosentyx in 2022, and reported any qualifying price increases for Cosentyx in 2021 and 2023, reported any qualifying price increases for other drugs but not Cosentyx in 2024, and did not report any qualifying price increases in 2022.[17]

Colorado All Payer Claims Database Transparency Reporting Information

Pursuant to section 10-16-1405(1)(a)(IV), C.R.S., each carrier and PBM must report the 15 prescription drugs that caused the greatest increases in the carrier's premiums in a given year. Please find data gathered from 19 payers pursuant to section 10-16-1405(1)(a)(IV), C.R.S., below.[18]

[14] https://data.chhs.ca.gov/dataset/prescription-drugs-introduced-to-market.
[15] https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases.
[16] https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/about.
[17] https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview
[18] Information submitted per section 10-16-1405, C.R.S. is required by all submitters to the APCD. For this submission, 19 submitters provided information.

Figure O-5

Payer Rank of Cosentyx Impact on Premiums in 2022

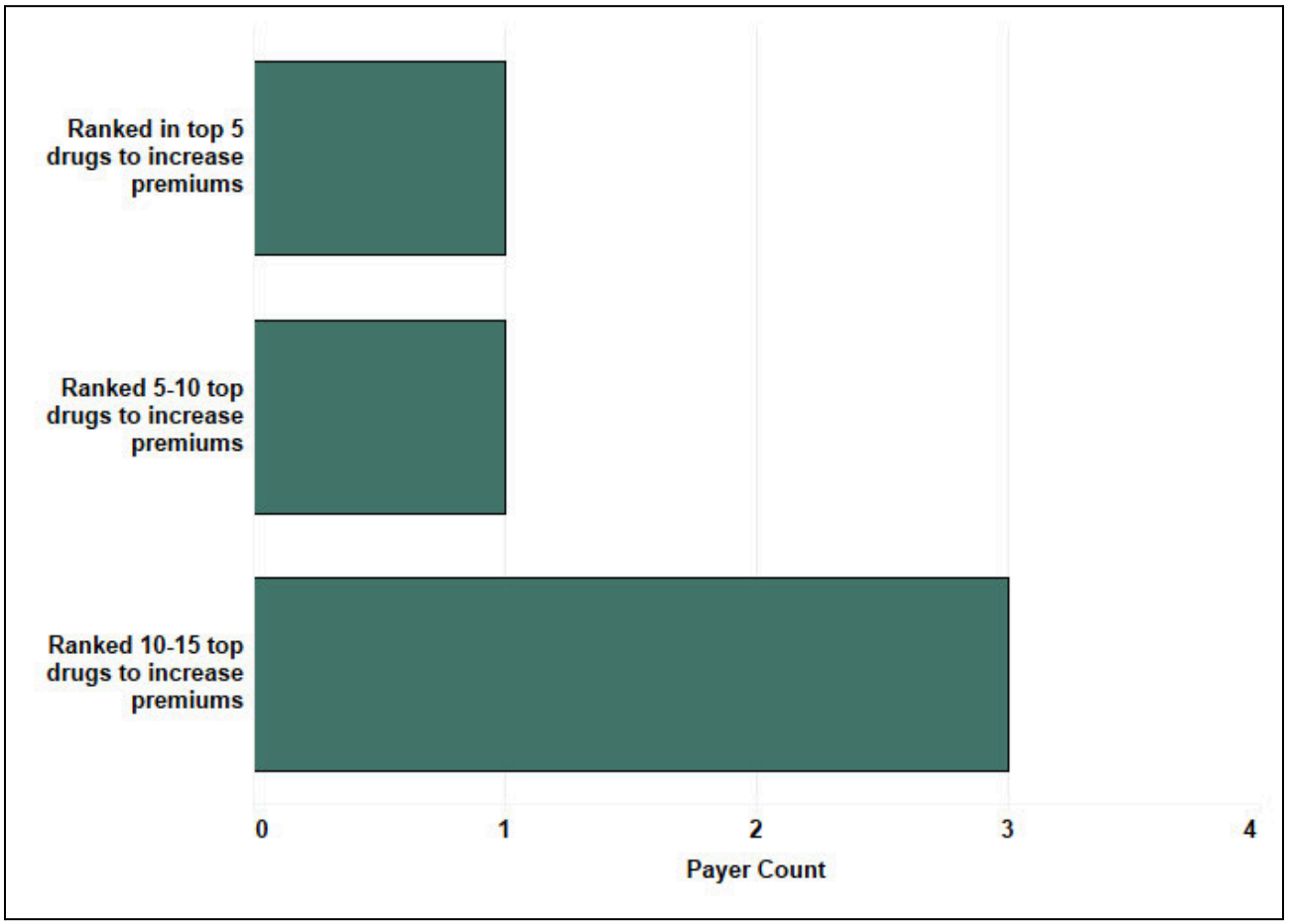

Figure O-5 shows the number of payers that ranked Cosentyx in the top 15 prescription drugs that increased premiums. Three of nineteen payers indicated that Cosentyx was in the top 10-15 drugs to increase premiums in 2021.

Payers and Pharmacy Benefit Management Firms were required to identify in their submission which 15 drugs caused the highest increases to premiums, however, no additional information was required pursuant to section 10-16-1405(1)(a)(IV), C.R.S. As a result, the specific dollar impact Cosentyx had on premiums, or even how its rank compared to other prescription drug premium impacts, is unknown.

While this information can be insightful in understanding Cosentyx's impact to a broader portion of the health care system, Board staff do not recommend the Board heavily weigh this information this year. Per section 10-16-1405, C.R.S., only the top drugs are submitted for each

reference, and more data and research would be necessary to understand the actual impacts to premiums and relative impact of each drug for each carrier.

Manufacturer Pricing Information

The SEC requires that foreign public companies file a Form 20-F each year.[19] This form provides a financial snapshot of the company's revenues, assets, and liabilities for the previous year. Novartis' 2023 20-F details that global net sales of Cosentyx reached $4.788 in 2022, a 1% increase from $4.718 in 2021. This includes $2.770 billion in U.S. sales and $2.018 billion internationally.[20] In 2023, Novartis reported total sales of Cosentyx were $4.980 billion, a 4% increase from $4.788 billion in 2022, including $2.636 billion in U.S. sales and $2.344 billion internationally.[21] The company attributes the sales increase in Cosentyx due to "continued demand growth across key regions, partly offset by revenue deduction increases in the US."[22] Additional information of estimates of Cosentyx's share of Novartis' total sales is contained in Appendix K.[23]

[19] Novartis is an international company and files a Form 20-F rather than a 10-K.

[20] https://www.sec.gov/Archives/edgar/data/1114448/000137036824000004/nvs-20231231.htm (pg. 56)

[21] https://www.sec.gov/Archives/edgar/data/1114448/000137036824000004/nvs-20231231.htm (pg. 46)

[22] https://www.sec.gov/Archives/edgar/data/1114448/000137036824000004/nvs-20231231.htm (pg. 47)

[23] Appendix K contains information on Cosentyx' estimated net national sales, whereas this appendix contains information for national and international sales.

Appendix P

Data Sources and Limitations

Data sources and limitations are described in detail here. How these data sources are used and component-specific limitations are outlined in each component's appendix.

All-Payer Claims Database (APCD)

The All Payer Claims Database (APCD) receives claims from Medicaid, Medicare Advantage, and over 40 commercial payers and represents over 4.5 million lives and over 75% of insured Coloradans. The APCD does not have claims data for uninsured Coloradans and some commercial payers and plans. For this affordability review, pharmacy and medical claims from January 2018 through December 2022, which were paid through May 2023, were used for analyses. Drugs are identified on pharmacy claims with their National Drug Code (NDC). APCD claims are categorized by the submitting payer and are categorized as Medicaid, Medicare Advantage, and all other submitters are commercial. Cosentyx and identified therapeutic alternatives NDC codes found in the APCD and utilized in these analyses were:

Drug Name	NDC
Cosentyx	00078-0639-41, 00078-0639-68, 00078-0639-97, 00078-0639-98, 00078-1056-97, 00078-1070-68, 00078-1168-61
Bimzelx	50474-0780-79, 50474-0781-85
Ilumya	47335-0177-01, 47335-0177-10, 47335-0177-95, 47335-0177-96
Omvoh	00002-7575-01, 00002-8011-01, 00002-8011-27
Siliq	00187-0004-00, 000187-0004-02
Skyrizi	00074-1050-01, 00074-1065-01, 00074-1066-01, 00074-1069-01, 00074-1070-01, 00074-2100-01, 00074-5015-01
Stelara	57894-0054-27, 57894-0060-02, 57894-0060-03, 57894-0061-03
Taltz	00002-1445-01, 00002-1445-09, 00002-1445-11, 00002-1445-27, 00002-7724-01, 00002-7724-11
Tremfya	57894-0640-01, 57894-0640-11

Limitations

- As the APCD does not include claims for all Coloradans, it is a conservative estimate, where utilizers, claims, and associated paid amounts are under-represented.
- Annual estimates of utilization are also likely under-represented as individuals change insurance and move and their entire year of utilization may not be captured in the APCD claims.
- Under federal and state privacy laws, information about drugs with fewer than 12 utilizers in the database must be protected, as it is potentially identifiable at such low numbers. Where utilization is below 12 individuals there will be less information available.
- One commercial payer reported inaccurate units for pharmacy claims. These units were removed, and any calculations using units did not include units from this payer. Dollar amounts and utilization information was reported accurately by this payer and were not removed. The only data element in the affordability review that incorporates units is the course of treatment calculation, which excludes this payer and is therefore an underestimate of the course of treatment.

- Pharmacy claims do not include diagnosis codes. As such, utilization and paid amount analyses were conducted for all Cosentyx utilization and separate analyses were not conducted for each FDA-approved indication.

First DataBank AnalySource

AnalySource provides WAC and other pricing benchmarks for all NDCs at current rates and historic levels. Cosentyx NDC codes found in AnalySource are listed in table P-1 above.

Limitations

- WAC and other data elements from AnalySource are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- WAC data is updated daily, but other data sources have a greater time lag, meaning that there are NDCs for which there is WAC data, but no utilization data. It is noted when these are included.

SSR Health

- Board staff contracted with SSR Health[1] to receive their proprietary U.S. prescription brand drug pricing and analytics net price database, which provides total net revenue and volume estimates for the majority of active brand name prescription drugs in the United States. SSR Health uses net revenues from publicly-available SEC Form 10-K financial reports from drug makers or other public sources to develop a net sales and gross-to-net estimates quarterly for all drugs.[2] The gross-to-net estimates provide a quarterly estimated gross-to-net percent rebate that is inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support. SSR Health provides these estimates on a total, statutory Medicaid, and total less statutory Medicaid basis.

Limitations

- Estimates are proprietary and confidential and may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.
- Gross-to-net sales estimates are inclusive of all concessions and discounts that manufacturers deduct from gross sales. This is inclusive of all rebates, 340B discounts, and point of sale copayment support, but cannot provide detailed amounts on these discounts.
- Estimates are for national information and are not specific to Colorado.

[1] SSR Health: https://www.ssrhealth.com/

[2] "Best Practices Using SSR Health Net Drug Pricing Data", Health Affairs Forefront, March 10, 2022. DOI: 10.1377/forefront.20220308.712815: https://www.healthaffairs.org/content/forefront/best-practices-using-ssr-health-net-drug-pricing-data