PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Cosentyx Subcutaneous Prior Authorization Policy
- Cosentyx® (secukinumab subcutaneous injection – Novartis)

REVIEW DATE: 10/29/2025; selected revision 03/18/2026, 04/29/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Cosentyx subcutaneous, an interleukin (IL)-17A antagonist, is indicated for the following uses:[1]

- **Enthesitis-related arthritis**, in patients ≥ 4 years of age with active disease.
- **Hidradenitis suppurativa**, in patients ≥ 12 years of age with moderate to severe disease.
- **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in patients ≥ 2 years of age with active disease.
- **Ankylosing spondylitis**, in patients ≥ 12 years of age with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.

In the pivotal trial for non-radiographic axial spondyloarthritis, patients were required to have objective signs of inflammation, indicated by elevated C-reactive protein and/or sacroiliitis on magnetic resonance imaging.

Guidelines
Il-17 blockers are mentioned in multiple guidelines for treatment of inflammatory conditions.

- **Enthesitis-Related Arthritis:** Guidelines for juvenile idiopathic arthritis from the American College of Rheumatology (ACR) [2018] address treatment of enthesitis-related arthritis.[14] These recommendations were developed prior to approval of Cosentyx. A tumor necrosis factor inhibitor (TNFi) is recommended over the use of methotrexate or sulfasalazine in those who have tried a nonsteroidal anti-inflammatory drug (NSAID).
- **Plaque Psoriasis:** Joint guidelines of care for the management and treatment of psoriasis with biologics were published by the American Academy of Dermatology (AAD) and the National Psoriasis Foundation (2019).[3] All of the biologics are generally recommended for treatment of moderate to severe disease. The AAD also recommends methotrexate (unless contraindicated) and other systemic therapies for treatment of moderate to severe psoriasis.[4] Traditional systemic agents can benefit widespread psoriasis. Studies have assessed response to methotrexate following 6 weeks to 4 months of treatment. Guidelines from the European Dermatology Forum (2025) recommend biologics (including Cosentyx) as second-line therapy for most patients requiring systemic treatment when there is inadequate response, contraindication, or intolerance to conventional systemic agents (e.g., methotrexate, cyclosporine, acitretin).[15]
- **Psoriatic Arthritis:** Guidelines from ACR/National Psoriasis Foundation (2018) generally recommend TNFis as the first-line treatment strategy over other biologics (e.g., IL-17 blockers) with differing mechanisms of action.[5]
- **Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondyloarthritis are published by the ACR/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] Following primary nonresponse to a TNFi, either Cosentyx or Taltz® (ixekizumab injection) is recommended; however, if the patient is a secondary nonresponder, a second TNFi is recommended over switching out of the class. In patients with a contraindication to a TNFi, use of an IL-17 blocker is recommended over traditional oral agents such as methotrexate or sulfasalazine.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Cosentyx subcutaneous. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cosentyx subcutaneous as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cosentyx subcutaneous to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Cosentyx® subcutaneous (secukinumab subcutaneous injection – Novartis)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR
   - **B)** Patient is Currently Receiving Cosentyx Subcutaneous or Intravenous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on Cosentyx subcutaneous or intravenous for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx subcutaneous or intravenous is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least ONE of the following (a or b):
       - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous or intravenous); OR
         Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
       - **b)** Compared with baseline (prior to initiating Cosentyx subcutaneous or intravenous), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2. **Enthesitis-Related Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
     - **i.** Patient is ≥ 4 years of age; AND
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR
   - **B)** Patient is Currently Receiving Cosentyx Subcutaneous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on Cosentyx subcutaneous for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx subcutaneous is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least ONE of the following (a or b):
       - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous); OR
         Note: Examples of objective measures include the Juvenile Arthritis Disease Activity Score (JADAS); Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
       - **b)** Compared with baseline (prior to initiating Cosentyx subcutaneous), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, improved function or activities of daily living.

3. **Hidradenitis Suppurativa.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i, ii, and iii):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient has tried at least one other therapy; AND
       Note: Examples include intralesional or oral corticosteroids (e.g., triamcinolone, prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), and isotretinoin.
     - **iii.** The medication is prescribed by or in consultation with a dermatologist; OR
   - **B)** Patient is Currently Receiving Cosentyx Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient has been established on Cosentyx subcutaneous for at least 3 months; AND
       Note: A patient who has received < 3 months of therapy or who is restarting therapy with Cosentyx subcutaneous is reviewed under criterion A (Initial Therapy).
     - **ii.** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous); AND
       Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index.
     - **iii.** Compared with baseline (prior to initiating Cosentyx subcutaneous), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.

4. **Non-Radiographic Axial Spondyloarthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has objective signs of inflammation, defined as at least ONE of the following (a or b):
       - **a)** C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
       - **b)** Sacroiliitis reported on magnetic resonance imaging; AND
     - **iii.** The medication is prescribed by or in consultation with a rheumatologist; OR
   - **B)** Patient is Currently Receiving Cosentyx Subcutaneous or Intravenous. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on Cosentyx subcutaneous or intravenous for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx subcutaneous or intravenous is reviewed under criterion A (Initial Therapy).
     - **ii.** Patient meets at least ONE of the following (a or b):
       - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous or intravenous); OR
         Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
       - **b)** Compared with baseline (prior to initiating Cosentyx subcutaneous or intravenous), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

5. **Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):
     - **i.** Patient is ≥ 6 years of age; AND
     - **ii.** Patient meets ONE of the following conditions (a or b):
       - **a)** Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
         Note: Examples include methotrexate, cyclosporine, or acitretin, A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (other than Cosentyx), Otezla/Otezla XR (apremilast tablets/extended-release tablets), or Sotyktu (deucravacitinib tablets). A biosimilar of Cosentyx does not count. Refer to **Appendix** for examples of biologics used for psoriasis. A patient who has already tried a biologic for

psoriasis, Otezla/Otezla XR, or Sotyktu is not required to "step back" and try a traditional systemic agent for psoriasis.

b) According to the prescriber, the patient has a contraindication to methotrexate; AND

iii. The medication is prescribed by or in consultation with a dermatologist; OR

B) Patient is Currently Receiving Cosentyx Subcutaneous. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has been established on Cosentyx subcutaneous for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cosentyx subcutaneous) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND

iii. Compared with baseline (prior to initiating Cosentyx subcutaneous), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

6. Psoriatic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

i. Patient is ≥ 2 years of age; AND

ii. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist; OR

B) Patient is Currently Receiving Cosentyx Subcutaneous or Intravenous. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has been established on Cosentyx subcutaneous or intravenous for at least 6 months; AND
Note: A patient who has received < 6 months of therapy with Cosentyx subcutaneous or intravenous or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Cosentyx subcutaneous or intravenous); OR
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating Cosentyx subcutaneous or intravenous), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

CONDITIONS NOT COVERED

- **Cosentyx® subcutaneous (secukinumab subcutaneous injection – Novartis)**

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

2. **Crohn's Disease.** Exacerbations of Crohn's disease, in some cases serious, occurred in clinical trials in patients treated with Cosentyx.[1] In a Phase II published study in patients with Crohn's disease (n = 59), an intravenous formulation of Cosentyx did not reduce the Crohn's disease activity index by ≥ 50 points compared with placebo and the study was terminated prematurely.[6]

3. **Rheumatoid Arthritis.** In a published, double-dummy Phase III study, Cosentyx was less effective than current treatments in patients with rheumatoid arthritis who were previously treated with a tumor necrosis factor inhibitor (TNFi).[7] Patients were randomized to one of four treatment groups: 1) induction with an intravenous formulation of Cosentyx (10 mg/kg) followed by Cosentyx 150 mg subcutaneously given once every 4 weeks (Q4W) [n = 137]; 2) secukinumab intravenous induction (10 mg/kg) followed by Cosentyx 75 mg subcutaneously Q4W (n = 138); 3) Orencia intravenous; or 4) placebo. At Week 24, ACR 20 response was significantly better with Cosentyx 150 mg subcutaneous (31%) vs. placebo (18%). ACR 20 response with Cosentyx 75 mg was 28%, which was not significantly better than the placebo group. ACR 50/70 responses were 17%/10%, respectively, with Cosentyx 150 mg and 12%/5%, respectively, with Cosentyx 75 mg which were not significantly different from that of placebo (9%/5%, respectively). The group treated with Orencia intravenous had significantly improved ACR 50/70 responses at Week 24 (28%/12%). Using as observed data, ACR 20/50/70 responses at Week 52 were 63%/46%/19%, respectively, with Cosentyx 150 mg, 57%/26%/7%, respectively, with Cosentyx 75 mg, and 75%/52%/23%, respectively, with Orencia intravenous. There is a published Phase II dose-ranging study (n = 237) evaluating Cosentyx in rheumatoid arthritis.[8-10] The ACR 20 response at Week 16 (using last observation carried forward analysis) was 34%, 46.9%, 46.5%, 53.7% for the 25, 75, 150, and 300 mg doses, respectively, vs. 36% for placebo; however, this did not achieve statistical significance. After Week 16, patients who responded to Cosentyx had sustained response through Week 52, with patients on the 150 mg dose having the greatest improvement over time (55% and 40% of patients with ACR 50 and ACR 70 responses, respectively, at Week 52). In another Phase II study, Cosentyx did not achieve higher ACR 20 response rates at Week 12 vs. placebo.[11] There was an open-label treatment period where ACR responses were generally maintained through Week 52. Some patients were treated with an intravenous formulation of secukinumab and generally responded similarly to those treated with Cosentyx. In another Phase II study, an intravenous formulation of secukinumab demonstrated limited efficacy in biologic-naïve patients with rheumatoid arthritis associated with the HLA-DRB1 allele.[12]

4. **Uveitis.** Efficacy is not established for this condition. There was not a statistically significant difference between Cosentyx subcutaneous and placebo in three Phase III studies that included patients with Behcet's uveitis (n = 118); active, noninfectious, non-Behcet's uveitis (n = 31); and quiescent, noninfectious, non-Behcet's uveitis (n = 125) [SHEILD, INSURE, and ENDURE studies, respectively].[13]

REFERENCES

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HISTORY

Type of Revision	Summary of Changes	Review Date

Early Annual Revision	Policy name was updated to specify this is for the subcutaneous formulation of Cosentyx. **Enthesitis-Related Arthritis:** For a patient currently receiving Cosentyx, it was clarified this applies to the subcutaneous formulation. **Plaque Psoriasis:** For a patient currently receiving Cosentyx, it was clarified this applies to the subcutaneous formulation. **Psoriatic Arthritis:** For a patient currently receiving Cosentyx, it was clarified this applies to the subcutaneous or intravenous formulation. **Ankylosing Spondylitis:** For a patient currently receiving Cosentyx, it was clarified this applies to the subcutaneous or intravenous formulation. **Non-Radiographic Axial Spondyloarthritis:** For a patient currently receiving Cosentyx, it was clarified this applies to the subcutaneous or intravenous formulation.	11/01/2023
Selected Revision	**Hidradenitis Suppurativa:** This condition and criteria for approval was added to the policy.	11/15/2023
Selected Revision	**Hidradenitis Suppurativa:** For a patient currently taking Cosentyx subcutaneous, the timeframe for established on therapy was changed from 90 days to 3 months. **Plaque Psoriasis:** For a patient currently taking Cosentyx subcutaneous, the timeframe for established on therapy was changed from 90 days to 3 months.	03/27/2024
Selected Revision	**Ankylosing Spondylitis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Non-Radiographic Axial Spondyloarthritis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Plaque Psoriasis:** In the Note, psoralen plus ultraviolet A light (PUVA) was removed from the examples of traditional systemic therapies. An additional Note was added that a 3-month trial of PUVA counts as a traditional systemic therapy. **Conditions Not Covered:** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).	09/11/2024
Annual Revision	No criteria changes.	11/20/2024

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Plaque Psoriasis:** For initial therapy, in the Note, a 3-month trial or prior intolerance to Otezla/Otezla XR (apremilast tablets/extended-release tablets) or Sotyktu (deucravacitinib tablets) was added as an exception to the requirement for a trial of one traditional systemic agent for psoriasis. For initial therapy, the requirement "patient has a contraindication to methotrexate, as determined by the prescriber" was modified to "according to the prescriber, the patient has a contraindication to methotrexate". In the Appendix, Otezla XR (apremilast extended-release tablets) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecular Drugs.	10/29/2025
Selected Revision	**Hidradenitis Suppurativa:** For initial therapy, the requirement that the patient is ≥ 18 years of age was changed to the patient is ≥ 12 years of age.	03/18/2026
Selected Revision	**Ankylosing Spondylitis:** For initial therapy, the requirement that the patient is ≥ 18 years of age was changed to the patient is ≥ 12 years of age.	04/29/2026

	In the Appendix, Icotyde (icotrokinra tablets) was added under the Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs.	

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, JIA, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilars; Actemra SC, biosimilars)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	PJIA, RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	AS, nr-axSpA, PsA, PsO
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Icotyde™ (icotrokinra tablets)	Inhibition of IL-23 receptor	PsO
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Otezla XR™ (apremilast extended-release tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD

Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO, PsA
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.