MEDICAL MUTUAL®

Drug Policy

Policy:	**201508**	**Initial Effective Date: 04/30/2015**
Code(s):	**HCPCS J3590**	**Annual Review Date: 12/19/2024**
SUBJECT:	**Cosentyx ® (secukinumab injection for subcutaneous use)**	**Last Revised Date: 12/19/2024**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

Overview

Cosentyx, a human interleukin (IL)-17A antagonist, is indicated for moderate to severe plaque psoriasis, active psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis and ankylosing spondylitis (As) in adults.[1] It is a recombinant human monoclonal Immunoglobulin G (IgG)1/κ antibody binds specifically to the IL-17A cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine involved in normal inflammatory and immune responses; therefore, Cosentyx inhibits the release of proinflammatory cytokines and chemokines. The recommended dose for plaque psoriasis is 300 mg by subcutaneous (SC) injection at every week for five doses followed by 300 mg every 4 weeks thereafter. For some patients, a dose of 150 mg may be acceptable. Recommended dosing for active psoriatic arthritis (PsA) and ankylosing spondylitis (AS) is either: a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. For PsA, Psoriasis and AS, the dose can be increased to 300 mg if needed. Cosentyx is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique using the pen or prefilled syringe may self-inject when deemed appropriate.

Clinical Efficacy

The efficacy of Cosentyx was established in four placebo-controlled, Phase III pivotal studies that compared both 150 mg and 300 mg of Cosentyx with placebo in patients with moderate to severe plaque psoriasis and who were candidates for phototherapy or systemic therapy; one study also used Enbrel® (etanercept for SC injection) as an active control. Each study assessed induction therapy with an assessment at Week 12 and maintenance therapy with an assessment at Week 52.[1-5] The four pivotal trials were of similar design with baseline demographic and baseline clinical characteristics of the patients in each study generally consistent and balanced across the treatment groups for baseline characteristics. Cosentyx was superior to the comparators (Enbrel® [etanercept for SC injection] and/or placebo) with respect to all coprimary and key secondary

endpoints, including psoriasis area and severity index (PASI) 75/90/100 responses and modified investigator's global assessment (mIGA).

Warnings and Precautions

Warnings/Precautions for Cosentyx include infections, pre-treatment evaluation for tuberculosis, exacerbation of Crohn's disease, hypersensitivity reactions, risk of hypersensitivity in latex-sensitive individuals, and vaccinations.

POLICY STATEMENT

This policy involves the use of Cosentyx. Prior authorization is recommended for medical benefit coverage of Cosentyx. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Cosentyx as well as the monitoring required for AEs and long-term efficacy, initial approval requires Cosentyx be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. **Cosentyx is subject to the Inflammatory Conditions Care Value Program for pharmacy benefits.**

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cosentyx is recommended in those who meet the following criteria:

1. **Ankylosing Spondylitis.** Approve if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if prescribed by or in consultation with a rheumatologist.
   - **B)** Patient is Currently Receiving Cosentyx. Approve if the patient meets BOTH of the following (i and ii):
     - **i.** Patient has been established on therapy for at least 6 months; AND
       Note: A patient who has received < 6 months of therapy 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); 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 Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating Cosentyx), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

Dosing in Ankylosing Spondylitis (AS). The recommend dose is a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. [1] If the patient continues to have active AS, dosages of 300mg every 4 weeks can be considered.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

2. Non-Radiographic Axial Spondyloarthritis. Approve if the patient meets ONE of the following (A or B):
A) Initial Therapy. Approve if the patient meets BOTH of the following (i and ii):
i. 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
ii. The medication is prescribed by or in consultation with a rheumatologist.
B) Patient is Currently Receiving Cosentyx. Approve if the patient meets BOTH of the following (i and ii):
i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy 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); 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 Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b) Compared with baseline (prior to initiating Cosentyx, patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

Dosing in Non-radiographic Axial Spondyloarthritis (nr-axSpA). The recommend dose is a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. [1]

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

3. **Plaque Psoriasis.** Approve if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve if the patient meets ALL 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 at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
   Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). 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. 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 is not required to "step back" and try a traditional systemic agent for psoriasis.
   b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND
   iii. The medication is prescribed by or in consultation with a dermatologist.
   B) Patient is Currently Receiving Cosentyx. Approve if the patient meets ALL the following (i, ii, and iii):
   i. Patient has been established on therapy for at least 90 days; AND
   Note: A patient who has received < 90 days 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) 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), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

Dosing in Plaque Psoriasis.

Adults: The recommended dose is 300 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. Each 300 mg dose is given as 2 subcutaneous injections of 150 mg. For some patients, a dose of 150 mg may be acceptable.[1]

Pediatric Dosing: Recommended dosage based on body weight and administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter**.** For patients less than 50kg at time of dosing, 75 mg is the recommended dose. For patients greater than 50kg at time of dosing, 150mg is recommended.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months (90 days)
B) *Extended Approval:* 1 year (365 days)

4. **Enthesitis-Related Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve 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.

B) Patient is Currently Receiving Cosentyx. Approve if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx 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); 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), 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.

Dosing in Enthesitis-Related Arthritis: The recommended dosage is administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter.

- For patients weighting ≥ 15 kg and < 50kg the dose is 75mg
- For patients weighing ≥ 50kg the dose is 150mg

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

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

A) Initial Therapy. Approve if the patient is 2 years of age or older and Cosentyx is prescribed by or in consultation with a rheumatologist or a dermatologist.

B) Patient is Currently Receiving Cosentyx. Approve if the patient meets BOTH of the following (i and ii):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy 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); 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 Consortuium 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), 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.

Dosing in Psoriatic Arthritis (PsA). The recommend dose is a loading dose of 150 mg at weeks 0, 1, 2, 3, and 4 and 150 mg every four weeks thereafter or 150 mg every four weeks without a loading dose. [1] Dose may be increased to 300 mg if patient continues to have active disease.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

6. 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 ≥ 18 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.

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

i. Patient has been established on therapy for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with Cosentyx 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); 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), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.

Dosing in Hidradenitis Suppurativa. The recommend dose is a subcutaneous loading dose of 300 mg at weeks 0, 1, 2, 3, and 4 and 300 mg subcutaneously every 4 weeks thereafter. Dose may be increased to 300 mg every 2 weeks if patient continues to have active disease.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 3 months (90 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Cosentyx has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Cosentyx should not be administered in combination with another biologic agent for an inflammatory condition (e.g., Enbrel, Humira, Remicade, Stelara). Combination therapy with two biologic agents is generally not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.[8] Targeted synthetic DMARDs such as Otezla® (apremilast tablets) should not be used in combination with a biologic such as Cosentyx.[9] Note: This does NOT exclude the use of MTX (a conventional synthetic DMARD used to treat psoriasis) in combination with Cosentyx.

2. **Crohn's Disease.** Exacerbations of Crohn's disease, in some cases serious, occurred in clinical trials with Cosentyx-treated patients.[1] According to the manufacturer, Cosentyx is not being developed for treatment of Crohn's disease. In a Phase II published study in patients with Crohn's disease (n = 59), an IV formulation of Cosentyx did not reduce the Crohn's disease activity index (CDAI) by ≥ 50 points compared with placebo and the study was terminated prematurely.[10]

3. **Rheumatoid Arthritis (RA).** According to the manufacturer, Cosentyx is not being developed for treatment of RA. There is a published Phase II dose-ranging study (n = 237) evaluating Cosentyx SC in RA.[12-14] The American College of Rheumatology (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 vs. 36% for placebo; however, this did not achieve statistical significance. After Week 16, patients who responded to Cosentyx sustained their 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).

4. **Uveitis.** Efficacy is not established for this condition. There was not a statistically significant difference between Cosentyx SC 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].[15]

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a

pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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Prior approval is required for HCPCS Code J3590†.

†When *unclassified biologics* (J3590) is determined to be Cosentyx.

Edits and Denials:

MEDICAL MUTUAL®

Drug Policy

Prior approval: Prior approval is required for Cosentyx **(HCPCS Code J3590)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

HCPCS Code(s):	
J3590	Unclassified biologics

Appendix A

Biologic or Targeted Synthetic DMARD	Mechanism of Action	Indications
Cimzia® (certolizumab pegol for SC injection)	Inhibition of TNF	AS, ASpA ,CD, PPs, PsA, RA
Enbrel® (etanercept for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Erelzi™ (etanercept-szzs for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Humira® (adalimumab for SC injection)	Inhibition of TNF	AS, CD, HS, PPs, RA, UC, UV
Amjevita™ (adalimumab-atto for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Cyltezo® (adalimumab-adbm for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Simponi® (golimumab for SC injection)	Inhibition of TNF	AS, PsA, RA, UC
Simponi® Aria™ (golimumab for IV infusion)	Inhibition of TNF	AS, PsA, RA, UC
Remicade® (infliximab for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Inflectra™ (infliximab-dyyb for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Renflexis® (infliximab-abda for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Actemra® (tocilizumab for IV infusion)	Inhibition of IL-6	CRS, GCA, RA
Actemra® (tocilizumab for SC injection)	Inhibition of IL-6	CRS, GCA, RA
Kevzara® (sarilumab for SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept for IV infusion)	T-cell costimulation modulator	PsA, RA
Orencia® (abatacept for SC injection)	T-cell costimulation modulator	PsA, RA
Rituxan® (rituximab for IV infusion)	CD20-directed cytolytic antibody	Various
Kineret® (anakinra for subcutaneous SC injection)	Inhibition of IL-1	NOMID, RA
Stelara® (ustekinumab for SC injection)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Stelara® (ustekinumab for IV infusion)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PPs
Cosentyx™ (secukinumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Taltz® (ixekizumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Ilumya™ (tildrakizumab-asmn for SC injection)	Inhibition of IL-23	PPs

Tremfya® (guselkumab for SC injection)	Inhibition of IL-23	PPs
Otezla® (apremilast tablets)	Inhibition of PDE4	BD, PPs, PsA
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways	RA
Xeljanz®, Xeljanz XR (tofacitinib tablets, tofacitinib ER tabs)	Inhibition of the JAK pathways	PsA, RA, UC

Agents and associated indications are for reference only.

"The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding."

AS = Ankylosing Spondylitis, ASpA = Axial Spondyloarthritis, BD = Behcet Disease, CD = Crohn's Disease, CRS = Cytokine Release Syndrome, GCA = Giant Cell Arteritis, GVHD = Graft-Versus-Host Disease, HS = Hidradenitis Suppurativa, NOMID = Neonatal-onset Multisystem Inflammatory Disease, PPs = Plaque Psoriasis, PsA = Psoriatic Arthritis, RA = Rheumatoid Arthritis, SpA = Spondyloarthritis, UC = Ulcerative Colitis, UV = Uveitis