MEDICAL MUTUAL®

Drug Policy

Policy:	**231201**	**Initial Effective Date: 01/18/2024**
Code(s):	**C9166**	**Annual Review Date: 01/16/2025**
SUBJECT:	**Cosentyx ® (secukinumab injection for intravenous use)**	**Last Revised Date:01/16/2025**

☒Subject to Site of Care

OVERVIEW

Cosentyx intravenous, an interleukin (IL)-17A antagonist, is indicated in the following conditions:

- **Psoriatic arthritis**, in adults with active disease.
- **Ankylosing spondylitis**, in adults with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.

POLICY STATEMENT

This policy involves the use of Cosentyx intravenous. Prior authorization is recommended for pharmacy benefit coverage of Cosentyx Intravenous. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. 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 intravenous as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cosentyx intravenous 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Ankylosing Spondylitis.** 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, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The medication is prescribed by or in consultation with a rheumatologist.
     - **iii.** Patient has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz, and Xeljanz/XR [documentation required]. Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple

adalimumab products counts as ONE product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product. A trial of Cimzia, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required].

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

i. Patient has been established on Cosentyx intravenous or subcutaneous for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx intravenous or 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 intravenous or subcutaneous); 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 intravenous or subcutaneous), 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 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter or 1.75 mg/kg by intravenous infusion every 4 weeks.[1] Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in adults with AS.

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

2. Non-Radiographic Axial Spondyloarthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):

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.

iv. Patient has tried TWO of Cimzia, Taltz, and Rinvoq [documentation required]. Note: A trial of Enbrel, an adalimumab product (e.g., Humira, Abrilada, adalimumab-adaz, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry), an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts [documentation required]. A trial of multiple adalimumab products counts as ONE product.

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

i. Patient has been established on Cosentyx intravenous or subcutaneous for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Cosentyx intravenous or 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 intravenous or subcutaneous); 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 intravenous or subcutaneous), 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 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter or 1.75 mg/kg by intravenous infusion every 4 weeks. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in adults with nr-axSpA.

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

3. 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 meets both of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

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

iii. Patient has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi subcutaneous, Stelara subcutaneous, Taltz, Tremfya, and Xeljanz/XR [documentation required]. Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi [documentation required]. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product.

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

i. Patient has been established on Cosentyx intravenous or subcutaneous for at least 6 months; AND

Note: A patient who has received < 6 months of therapy with Cosentyx intravenous or subcutaneous 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 intravenous or subcutaneous); 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 intravenous or subcutaneous), 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

Dosing in Psoriatic Arthritis (PsA). The recommend dose is a loading dose of 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter or 1.75 mg/kg by intravenous infusion every 4 weeks. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in adults with PsA.

Initial Approval/ Extended Approval.
A A) *Initial Approval:* 6 months (180 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 intravenous should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition (See Appendix for examples). Combination therapy is generally not recommended due to the potential for a higher rate of adverse effects with combination therapies and lack of evidence for additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Cosentyx intravenous.

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.[4]

3. **Enthesitis-Related Arthritis.** Cosentyx subcutaneous is indicated and has approved dosing regimens for treatment of enthesitis-related arthritis.[1]

4. **Plaque Psoriasis.** Cosentyx subcutaneous is indicated and has approved dosing regimens for treatment of plaque psoriasis.[1]

5. **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).[5] 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). At Week 24, ACR 20 response was significantly better with Cosentyx 150 mg subcutaneous (31%) and Orencia intravenous (43%) 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% with Cosentyx 150 mg and 12%/5% with Cosentyx 75 mg which was not significantly different from that of placebo (9%/5%). 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% with Cosentyx 150 mg, 57%/26%/7% with Cosentyx 75 mg, and 75%/52%/23% with Orencia intravenous. There is a published Phase II dose-ranging study (n = 237) evaluating Cosentyx in rheumatoid arthritis.[6-8] 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 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.[9] 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 subcutaneous. 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.[10]

6. 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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8. Strand V, Kosinski M, Gnanasakthy A, et al. Secukinumab treatment in rheumatoid arthritis is associated with incremental benefit in the clinical outcomes and HRQoL improvements that exceed minimally important thresholds. *Health Qual Life Outcomes*. 2014;12:31.
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10. Burmester GR, Durez P, Shestakova G, et al. Association of HLA-DRB1 alleles with clinical responses to the anti-interleukin-17A monoclonal antibody secukinumab in active rheumatoid arthritis. *Rheumatology (Oxford).* 2016;55(1):49-55.