Mass General Brigham
Health Plan

Cosentyx® (secukinumab)
Effective 11/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled through a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	Cosentyx IV is available via Medical Benefit ONLY Cosentyx subcutaneous Prefilled Syringe and Auto-Injector are available via Pharmacy Benefit Only		

Overview

Cosentyx (secukinumab) is an interleukin-17A antagonist indicated or the treatment of:

- Moderate to severe plaque psoriasis in patients 6 years of age and older who are candidates for systemic therapy or photo therapy
- Active psoriatic arthritis in patients 2 years of age and older
- Active ankylosing spondylitis in adults
- Non-radiographic axial spondyloarthritis with objective signs of inflammation in adults
- Enthesitis-related arthritis (ERA) in pediatric patients 4 years of age and older
- Moderate to severe hidradenitis suppurativa in adults

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorizations may be granted when all the following diagnosis-specific criteria are met:

Moderate to severe plaque psoriasis

1. The member has a diagnosis of moderate to severe plaque psoriasis
2. At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. The member meets ONE of the following criteria:
    a. Minimum duration of 4-week trial and failure, intolerance, or contraindication to ONE of the following topical therapies
        1. Corticosteroids (e.g., betamethasone, clobetasol)
        2. Vitamin D analogs (e.g., calcitriol, calcipotriene)

3. Tazarotene
4. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
5. Anthralin
6. Coal tar

b. The member has severe psoriasis that warrants a biologic DMARD as first-line therapy

4. Trial and failure, intolerance, or contraindication to ONE of the following:
   a. Cimzia
   b. Enbrel
   c. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp
   d. Skyrizi
   e. Stelara
   f. Tremfya

Active psoriatic arthritis (PsA)

1. The member has a diagnosis of active psoriatic arthritis (PsA)
2. Trial and failure, intolerance, or contraindication to ONE of the following:
   a. Cimzia
   b. Enbrel
   c. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp
   d. Rinvoq/Rinvoq LQ
   e. Simponi
   f. Skyrizi
   g. Stelara
   h. Tremfya
   i. Xeljanz/XR
3. The member has ONE of the following:
   a. Actively inflamed joints
   b. Dactylitis
   c. Enthesitis
   d. Axial disease
   e. Active skin and/or nail involvement

Active ankylosing spondylitis (AS)

1. The member has a diagnosis of ankylosing spondylitis
2. The member has experienced trial and failure, contraindication or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
3. Trial and failure, intolerance, or contraindication to ONE of the following:
   f. Cimzia
   b. Enbrel
   c. Humira, Hadlima, Adalimumab-adaz, Adalimumab-fkjp
   d. Rinvoq
   e. Simponi
   f. Xeljanz/XR

Axial spondyloarthritis (nonradiographic)

1. Member has a diagnosis of non-radiographical axial spondyloarthritis
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints)
3. The member has experienced trial and failure, contraindication or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
4. Trial and failure, intolerance, or contraindication to ONE of the following:
    a. Cimzia
    b. Rinvoq

Moderate to Severe Hidradenitis Suppurativa

1. Member has a diagnosis of moderate to severe hidradenitis suppurativa (Hurley stage II or III)
2. Trial and failure, intolerance, or contraindication to ONE of the following:
    a. Humira (Abbvie)
    b. Hadlima
    c. Adalimumab-adaz
    d. Adalimumab-fkjp

Enthesitis related arthritis (ERA)

1. The member is 4 years of age or older
2. The member has active ERA with both arthritis and enthesitis, arthritis alone, or enthesitis alone
3. The member has experienced trial and failure, contraindication or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.

NOTE: Children are excluded from this category if they have a first-degree relative with psoriasis, positive RF, or systemic arthritis.

Continuation of Therapy

Authorization may be granted for members who achieve or maintain positive clinical response with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 24 months
2. The following quantity limits apply:

Cosentyx 150mg	2 injections per 30 days
Cosentyx 300mg	1 injection per 30 days

References

1. Baeten D, Sieper J, Braun J, et al. Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. *N Engl J Med*. 2015;373(26):2534-48.
2. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; August 2024.
3. Deodhar A, Conaghan PG, Kvien TK, et al. Secukinumab provides rapid and persistent relief in pain and fatigue symptoms in patients with ankylosing spondylitis irrespective of baseline C-reactive protein levels or prior tumor necrosis factor inhibitor therapy: 2-year data from the MEASURE 2 study. Clin Exp Rheumatol 2018.

4. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
6. 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(9999):1137-46.
7. Pavelka K, Kivitz A, Dokoupilova E, et al. Efficacy, safety, and tolerability of secukinumab in patients with active ankylosing spondylitis: a randomized, double-blind phase 3 study, MEASURE 3. Arthritis Res Ther 2017; 19:285
8. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis*. Arthritis Rheumatol.* 2015: 10.1002/art.39298. [Epub ahead of print].

Review History

02/22/2016: Reviewed P&T Mtg
02/27/2017: Reviewed & Revised (added Step)
02/26/2018: Reviewed & Revised P&T Mtg
02/20/2019: Reviewed & Revised P&T Mtg
05/20/2020: Reviewed and Updated May P&T Mtg; overview and references updated; started and stabilized statement; added QL to criteria. Effective 7/1/20
11/18/2020: Reviewed; Updated criteria to have preferred agent for Comm/Exch strategy
01/19/2022: Reviewed and Updated for Jan P&T; added new indications & criteria for nonradiographic axial spondyloarthritis & ERA; references updated. Effective 03/01/2022.
06/14/2023: Reviewed and updated; Updated QL for Cosentyx 150mg to 2 injections per 30 days.
11/15/2023 – Reviewed and Updated at Nov P&T; For Psoriatic Arthritis: 5% BSA changed to at least 3%. Removed TB requirement. Updated preferred agents to prior use with ONE of the following agents: Cimzia, Enbrel, Humira or biosimilars, Skyrizi, Stelara, Tremfya. Updated topical therapies. For Psoriatic arthritis: Updated preferred agents to require previous use of TWO of the following: Cimzia**,** Enbrel, Humira or biosimilars, Rinvoq, Simponi, Skyrizi, Stelara, Tremfya, Xeljanz/XR, AND Cosentyx AND Orencia. Removed requirement of traditional DMARD. Removed appendix. Consolidated reauthorization criteria. Effective 1/1/2024
4/10/2024 – Reviewed and Updated for April P&T; Added Cosentyx IV to criteria. Effective 5/1/2024
09/11/2024 – Reviewed and updated for September P&T. Added Rinvoq LQ as a previous treatment option for psoriatic arthritis. Added criteria for hidradenitis suppurativa. Effective 11/1/2024.
10/09/2024 – Reviewed and updated for October P&T. Updated criteria for plaque psoriasis to remove requirement for documentation of medical records for trial and failure with conventional therapies. Effective 11/1/2024.