Mass General Brigham
Health Plan

Cosentyx® (secukinumab)
Effective 03/01/2022

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (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. Secukinumab inhibits the release of proinflammatory cytokines and chemokines

Coverage Guidelines

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

OR

Authorizations may be granted when all the following criteria have been met, and documentation is provided:

Moderate to severe plaque psoriasis

1. The member has a diagnosis of moderate to severe plaque psoriasis
2. At least 5% 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. Member meets any of the following criteria:
   a. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
      - 1 topical agent + 1 systemic agent (methotrexate, cyclosporine, or acitretin)
      - 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
      - 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
      - 2 systemic agents

b. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). See Appendix A
c. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

Active psoriatic arthritis (PsA)
1. The member has a diagnosis of active psoriatic arthritis (PsA)
2. One of the following:
    a. The member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
    b. The member has a contraindication to BOTH methotrexate AND leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Active ankylosing spondylitis (AS)
1. The member has a diagnosis of active ankylosing spondylitis (AS)
2. The member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
3. The member has an intolerance or contraindication to two or more NSAIDs.

Axial spondyloarthritis (nonradiographic)
1. The member is at least 18 years of age
2. The member has active nonradiographic axial spondyloarthritis with objective signs of inflammation (i.e. Redness, heat, swelling and pain)
3. The member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
4. The member has an intolerance or contraindication to two or more NSAIDs.

Enthesitis related arthritis (ERA)
1. The member is between 4 and 17 years of age
2. The member has active ERA with both arthritis and enthesitis, arthritis alone, or enthesitis alone
3. Member has TWO or more of the following:
    a. Sacroiliac joint tenderness or lumbosacral inflammatory pain
    b. Positive human leukocyte antigen (HLA)-B27
    c. First-degree relative with acute anterior uveitis, ankylosing spondylitis, inflammatory bowel disease with sacroiliitis, or reactive arthritis
    d. Acute anterior uveitis
    e. Onset of arthritis in males >6 years of age

3. The member has experienced an inadequate response to at least TWO non-steroidal anti-inflammatory (NSAID) drugs

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

<u>Continuation of Therapy</u>

Plaque psoriasis:

Authorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Psoriatic arthritis, ESA, Ankylosing spondylitis and Axial spondyloarthritis (nonradiographic):

Authorization may be granted for all members (including new members) who meet all initial authorization criteria and 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. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
   Note: Members who have received Cosentyx or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. The following quantity limits apply:

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

Appendices

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B: TNF Inhibitors Indicated for Psoriatic Arthritis

1. Cimzia (certolizumab pegol)
2. Enbrel (etanercept)
3. Humira (adalimumab)
4. Inflectra (infliximab-dyyb)
5. Renflexis (infliximab-abda)
6. Remicade (infliximab)
7. Simponi (golimumab)

References

1. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; December 2021
2. 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.
3. 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.
4. 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.

5. 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
6. 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].
7. 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.
8. 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.

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.