



Cosentyx® (secukinumab)
Effective 02/20/2019

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
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

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderate to severe plaque psoriasis (PsO)
2. Active psoriatic arthritis (PsA)
3. Active ankylosing spondylitis (AS)

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

A. Moderate to severe plaque psoriasis

1. Authorization may be granted for members who have previously received Cosentyx, Otezla, or any other biologic DMARD indicated for the treatment of moderate to severe plaque psoriasis.
2. Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:
 - a. 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.
 - b. Member meets any of the following criteria:

- i. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
 - o 1 topical agent + 1 systemic agent (methotrexate, cyclosporine, or acitretin)
 - o 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
 - o 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
 - o 2 systemic agents
- ii. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). See Appendix A
- iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

B. Active psoriatic arthritis (PsA)

1. Authorization may be granted for members who have previously received Cosentyx, Otezla, Stelara, or Taltz.
2. Authorization may be granted for treatment of active PsA when BOTH of the following criteria is met:
 - a. One of the following:
 - o Member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
 - o Member has experienced an intolerance to a trial of at least one TNF inhibitor indicated for PsA.
 - OR
 - o All TNF inhibitors indicated for PsA are not appropriate for the member (e.g., due to comorbidities or a history of infections).
- AND
- b. One of the following:
 - o Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
 - o Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

C. Active ankylosing spondylitis (AS)

1. Authorization may be granted for members who have previously received Cosentyx or any other biologic DMARD indicated for active ankylosing spondylitis.
2. Authorization of 24 months may be granted for treatment of active AS when any of the following criteria is met:
 - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
 - b. Member has an intolerance or contraindication to two or more NSAIDs.

Continuation of Therapy

A. For 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 after at least 3 months of



therapy with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

B. For psoriatic arthritis and ankylosing spondylitis:

Authorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Cosentyx as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals will be granted for 24 months
2. Reauthorizations will be granted for 24 months

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)

Other

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.

References

1. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2018
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 tumour 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

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.