Cosentyx® (secukinumab)
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ 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
Cosentyx is a human interleukin-17A antagonist indicated for the treatment of:
- Moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis (PsA)
- Adults with active ankylosing spondylitis (AS)
- Active nonradiographic axial spondyloarthritis (nr-axSpA) in adults with objective signs of inflammation
- Active enthesitis-related arthritis (ERA)

Coverage Guidelines
Authorization may be reviewed on a case by case basis 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
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Ankylosing Spondylitis and **Non-Radiographic Axial Spondyloarthritis**
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of **ONE** of the following:
    a. Ankylosing spondylitis
    b. Non-radiographic axial spondyloarthritis

2. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agent that is FDA-approved for the requested indication
4. Appropriate dosing †

Moderate-Severe Plaque Psoriasis
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of moderate to severe plaque psoriasis
2. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** conventional therapy or contraindication to **ALL** conventional therapies (see appendix B):
        i. topical agent
        ii. phototherapy
        iii. systemic agent
    b. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing †
4. Prescriber provides clinical rationale for use of Cosentyx® instead of Stelara®

Psoriatic Arthritis (PsA)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of psoriatic arthritis
2. **BOTH** of the following:
    a. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to Stelara®
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agent that is FDA-approved for the requested indication
3. Appropriate dosing †

Psoriatic Arthritis (PsA) in pediatric patients
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Psoriatic Arthritis in pediatric patients
2. Member is ≥ 2 years to < 18 years of age
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. Enbrel® (etanercept)
    b. Humira® (adalimumab)
4. Appropriate dosing †

Enthesitis-Related Arthritis (ERA)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of enthesis related arthritis
2. Member is ≥ 4 years to < 18 years of age
3. Appropriate dosing†

†*See Appendix C for more frequent or higher doses*

Off-Label Indications

Moderate to severe hidradenitis suppurativa

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe hidradenitis suppurativa
2. Paid claims within 6 months or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
3. **ALL** of the following:
    a. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to Humira® (adalimumab)
    b. Paid claims or physician attestation of inadequate response or adverse reaction to the **ONE** or contraindication to **ALL** of the following: unbranded infliximab, Kineret® (anakinra), Remicade® (infliximab), Avsola® (infliximab-axxq), Inflectra® (infliximab-dyyb) or Renflexis® (infliximab-abda)
    c. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to Stelara® (ustekinumab)

Pityriasis rubra pilaris (PRP)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of pityriasis rubra pilaris
2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** topical corticosteroid or contraindication to **ALL** topical corticosteroids
3. Clinical rationale for use of the requested agent instead of Stelara® and Taltz®

Synovitis-acne-pustulosis-hyperostosis-osteitis Syndrome (SAPHO)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of SAPHO
2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** NSAID or contraindication to **ALL** NSAIDs
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids
4. Clinical rationale for use of the requested agent instead of Stelara® (ustekinumab)

New members currently stable on Cosentyx® can be approved without documentation of failed trials with the conventional therapies.

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy and request can be recertified if dosing is appropriate.

Limitations

1. Initial approvals will be granted for the following based on diagnosis:
    a. Plaque psoriasis and off-label indications: 3 months
    b. All other diagnosis: 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

Cosentyx Inj 150mg/mL Cosentyx Pen Inj 150mg/mL	150mg (1mL) per 28 days

Cosentyx Inj 300mg dose Cosentyx Pen Inj 300mg dose	300mg (2mL) per 28 days

Appendix A. Dosing

Cosentyx® (secukinumab)	**Plaque Psoriasis** Adults - SQ: 300 mg initially at week 0, 1, 2, 3 and 4, followed by 300 mg every 4 weeks Pediatrics – SQ: < 50 kg – 75 mg at week 0, 1, 2, 3 and 4, followed by 75 mg every 4 weeks ≥ 50 kg – 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks **Psoriatic Arthritis (PsA)** Adults - SQ: 150 mg initially at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks, may consider dose of 300 mg if psoriatic arthritis continues Pediatrics – SQ: ⩾ 15 kg and < 50 kg – 75 mg at week 0, 1, 2, 3 and 4, followed by 75 mg every 4 weeks ⩾ 50 kg - 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks **Co-existent Plaque Psoriasis AND Psoriatic Arthritis** SQ: 300 mg initially at week 0, 1, 2, 3 and 4, followed by 300 mg every 4 weeks **Ankylosing Spondylitis (AS)** SQ: 150 mg initially at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks. May increase to 300 mg every 4 weeks **Non-Radiographic Axial Spondyloarthritis** SQ: 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks **Enthesitis-Related Arthritis (ERA)** SQ: ⩾ 15 kg and < 50 kg – 75 mg at week 0, 1, 2, 3 and 4, followed by 75 mg every 4 weeks SQ: ⩾ 50 kg - 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks

Appendix B. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors
Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix C. More Frequent/High Doses

Requests for more frequent or higher doses of injectable biologics may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:

a. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication

3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

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 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) P&T Mtg
03/01/2018: Reviewed & Revised (adopted MH RS) P&T Mtg
02/20/2019: Reviewed P&T Mtg
10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021
11/17/2021 – Reviewed and Updated for Nov P&T; matched MH UPPL; updated to reflect criteria changes based on literature; added appendix with diagnosis of hidradenitis supprativa and higher dose/more frequent dosing guidelines.
11/17/2021 – Updated per MH UPPL: criteria for Taltz revised for psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis based on contract. Additionally, recertification criteria regarding Cosentyx requests approved for ankylosing spondylitis or non-radiographic axial spondyloarthritis prior to Taltz require was removed as this is no longer a requirement in the criteria.

Effective 01/01/2022
06/22/2022 – Reviewed and Updated for June P&T; matched MH UPPL. Added criteria for newly FDA-approved indications: enthesitis-related arthritis (ERA) and PsA in pediatric patients. Continuation of therapy language was updated. Updated Appendices and References. Effective 08/01/22.
01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Off-label indications added for: HS, PRP, SAPHO. Added language regarding stability of requested medication for new members. Updated Appendix sections by removing off-label indications. Effective 3/1/23.

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