

**Cosentyx® (secukinumab)**  
Effective 08/01/2022

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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) in patients 2 years of age and older
- Adults with active ankylosing spondylitis (AS)
- Active nonradiographic axial spondyloarthritis (nr-axSpA) in adults with objective signs of inflammation
- Active enthesitis-related arthritis (ERA) in patients 4 years of age and older

### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners 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. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs
3. **ONE** of the following:



- a. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
- b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
4. Appropriate dosing (*See Appendix for more frequent or higher doses*)

#### Moderate-Severe Plaque Psoriasis

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

1. Appropriate diagnosis
2. **ONE** of the following:
  - a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** conventional therapy (see appendix B):
    - i. topical agent
    - ii. phototherapy
    - iii. systemic agent
  - b. Contraindication to **ALL conventional therapies**:
    - i. topical agent
    - ii. phototherapy
    - iii. systemic agent
  - c. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing (*See Appendix for more frequent or higher doses*)
4. Prescriber provides clinical rationale for use of Cosentyx<sup>®</sup> instead of Stelara<sup>®</sup>

#### Psoriatic Arthritis (PsA)

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

1. Appropriate diagnosis
2. **BOTH** of the following:
  - a. Paid claims or physician documented inadequate response, adverse reaction, or contraindication to Stelara<sup>®</sup>
  - b. **ONE** of the following:
    - i. Paid claims or physician documented inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication
    - ii. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication
3. Appropriate dosing (*See Appendix for more frequent or higher doses*)

#### Psoriatic Arthritis (PsA) in pediatric patients

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

1. Diagnosis of Psoriatic Arthritis (PsA) in pediatric patients
2. Member is  $\geq 2$  years to  $< 18$  years of age
3. Paid claims or physician documented Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
  - a. Enbrel<sup>®</sup> (etanercept)
  - b. Humira<sup>®</sup> (adalimumab)
4. Appropriate dosing (*See Appendix for more frequent or higher doses*)

#### Enthesitis-Related Arthritis (ERA)

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



1. Appropriate diagnosis
2. Member is  $\geq 4$  years to  $< 18$  years of age
3. Appropriate dosing (*See Appendix for more frequent or higher doses*)

**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: 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

**Appendices**

**Appendix A: Dosing**

<p>Cosentyx® (secukinumab)</p>	<p><b>Plaque Psoriasis</b>          Adults - SQ: 300 mg initially at week 0, 1, 2, 3 and 4, followed by 300 mg every 4 weeks          Pediatrics – SQ:              <math>&lt; 50</math> kg – 75 mg at week 0, 1, 2, 3 and 4, followed by 75 mg every 4 weeks              <math>\geq 50</math> kg – 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks</p> <p><b>Psoriatic Arthritis (PsA)</b>          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:              <math>\geq 15</math> kg and <math>&lt; 50</math> kg – 75 mg at week 0, 1, 2, 3 and 4, followed by 75 mg every 4 weeks              <math>\geq 50</math> kg - 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks</p> <p><b>Co-existent Plaque Psoriasis AND Psoriatic Arthritis</b>          SQ: 300 mg initially at week 0, 1, 2, 3 and 4, followed by 300 mg every 4 weeks</p> <p><b>Ankylosing Spondylitis (AS)</b>          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</p> <p><b>Non-Radiographic Axial Spondyloarthritis</b>          SQ: 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks</p> <p><b>Enthesitis-Related Arthritis (ERA)</b></p>
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	<p>SQ: <math>\geq 15</math> kg and <math>&lt; 50</math> kg – 75 mg at week 0, 1, 2, 3 and 4, followed by 75 mg every 4 weeks</p> <p>SQ: <math>\geq 50</math> kg - 150 mg at week 0, 1, 2, 3 and 4, followed by 150 mg every 4 weeks</p>
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### 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: Off-Label Indications

#### Hidradenitis Suppurativa (HS)

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

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II and Hurley Stage III disease)
2. Paid claims or physician documented inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline)
3. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Humira® (adalimumab) AND Stelara® (ustekinumab)
4. Paid claims or physician documented inadequate response, adverse reaction to ONE of the following or contraindication to ALL of the following:
  - a. Kineret® (anakinra)
  - b. Remicade® (infliximab)
  - c. Avsola® (infliximab-axxq)
  - d. Inflectra® (infliximab-dyyb)
  - e. Renflexis® (infliximab-abda)
5. Appropriate dosing: Cosentyx® (secukinumab) 300mg weekly for five weeks then 300 mg every four weeks

#### 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 documented 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 suppurativa 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.

### 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.