

Clinical Policy: Secukinumab (Cosentyx)

Reference Number: CP.PHAR.261

Effective Date: 08.16

Last Review Date: 11.18

Line of Business: HIM, Medicaid

[Coding Implications](#)[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Secukinumab (Cosentyx[®]) is an interleukin-17A (IL-17A) antagonist.

FDA Approved Indication(s)

Cosentyx is indicated for the treatment of:

- Moderate to severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy
- Adults with active psoriatic arthritis (PsA)
- Adults with active ankylosing spondylitis (AS)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Cosentyx is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Plaque Psoriasis** (must meet all):

1. Diagnosis of PsO;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of a \geq 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a \geq 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a \geq 3 consecutive month trial of adalimumab (*Humira[®] is preferred*), unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is required for adalimumab*
6. Dose does not exceed 300 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age \geq 18 years;
4. Member meets one of the following (a, b, or c), unless contraindicated or clinically significant adverse effects are experienced:
 - a. Failure of a \geq 3 consecutive month trial of MTX at up to maximally indicated doses;
 - b. If intolerance or contraindication to MTX (*see Appendix D*), failure of a \geq 3 consecutive month trial of cyclosporine, sulfasalazine, or leflunomide at up to maximally indicated doses;
 - c. For axial disease, failure of a \geq 4 week-trial of non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses;
5. Failure of etanercept (*Enbrel is preferred*) and adalimumab (*Humira is preferred*), each used for \geq 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is required for etanercept and adalimumab.*
6. Dose does not exceed one of the following (a or b):
 - a. PsA alone: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks;
 - b. PsA with PsO: 300 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks.

Approval duration: 6 months

C. Ankylosing Spondylitis (must meet all):

1. Diagnosis of AS;
2. Prescribed by or in consultation with a rheumatologist;
3. Age \geq 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for \geq 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept (*Enbrel is preferred*) and adalimumab (*Humira is preferred*) each used for \geq 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization is required for etanercept and adalimumab*
6. Dose does not exceed 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks.

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
 - a. PsO alone: 300 mg every 4 weeks;
 - b. PsA (i or ii):
 - i. 150 mg every 4 weeks;
 - ii. 300 mg every 4 weeks, if documentation supports inadequate response to a \geq 3 consecutive month trial of 150 mg every 4 weeks or member has coexistent PsO;
 - c. AS: 150 mg every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis	NSAID: non-steroidal anti-inflammatory drug
FDA: Food and Drug Administration	PsA: psoriatic arthritis
IL-17A: interleukin-17A	PsO: plaque psoriasis
MTX: methotrexate	

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane [®])	PsO 25 or 50 mg PO QD	50 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cyclosporine (Sandimmune [®] , Neoral [®])	PsO 2.5 – 4 mg/kg/day PO divided BID PsA* 2.5 – 3 mg/kg/day PO QD	PsO: 4 mg/kg/day PsA: 3 mg/kg/day
leflunomide (Arava [®])	PsA* 100 mg/day PO loading dose for 3 days followed by 20 mg/day PO	20 mg/day
methotrexate (Rheumatrex [®])	PsO 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week PsA* 7.5 – 15 mg/week PO	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	AS, PsA Varies	Varies
sulfasalazine (Azulfidine [®])	PsA* 2 g/day PO	5 g/day
Enbrel [®] (etanercept)	AS 50 mg SC once weekly PsA 25 mg SC twice weekly or 50 mg SC once weekly	50 mg/week
Humira [®] (adalimumab)	AS, PsA 40 mg SC every other week PsO <u>Initial dose:</u> 80 mg SC <u>Maintenance dose:</u> 40 mg SC every other week starting one week after initial dose	40 mg every other week

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): serious hypersensitivity reaction to secukinumab or to any of the excipients
- Boxed warning(s): none reported

Appendix C: General Information

- Definition of failure of MTX or DMARDs
 - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
 - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
 - Reduction in joint pain/swelling/tenderness
 - Improvement in ESR/CRP levels
 - Improvements in activities of daily living

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsO (with or without PsA)	300 mg SC at weeks 0, 1, 2, 3, and 4, followed by 300 mg SC every 4 weeks. (for some patients, a dose of 150 mg may be acceptable)	300 mg every 4 weeks
PsA	With loading dose: 150 mg SC at week 0, 1, 2, 3, and 4, followed by 150 mg SC every 4 weeks Without loading dose: 150 mg SC every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg.	300 mg every 4 weeks
AS	With loading dose: 150 mg SC at weeks 0, 1, 2, 3, and 4, followed by 150 mg SC every 4 weeks thereafter Without loading dose: 150 mg SC every 4 weeks	150 mg every 4 weeks

VI. Product Availability

- Single-dose Sensoready[®] pen: 150 mg/mL
- Single-dose prefilled syringe: 150 mg/mL
- Single-use vial: 150 mg

VII. References

1. Cosentyx Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2018. Available at <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/cosentyx.pdf>. Accessed September 4, 2018.
2. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KM, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic

- arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009 Sep; 6(3):451-85.
3. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May; 58 (5):826-50.
 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 Annals of the Rheumatic Diseases Published Online First: 07 December 2015. doi: 10.1136/annrheumdis-2015-208337.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.85.Psoriasis Treatments. Plaque psoriasis: removed criteria related to malignant disease and concurrent use with another biologic agent; removed Otezla as an option for failure of DMARD; removed duration of trial for topical and phototherapy; added requirement for trial and failure of Enbrel and Humira, unless contraindicated; added max dose; updated contraindications per FDA labeling; re-auth: modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement. For PsA: required trial of MTX and added requirement for the following if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. Added criteria for coverage of ankylosing spondylitis and psoriatic arthritis. Re-auth: Combined into All Indications; added max dose and reasons to discontinue; Modified approval duration to 6 months for initial approval and 12 months for continued approval.	06.16	08.16
Converted to new template. For PsO, preferencing requirement for Enbrel removed due to class review clinical guidance approved in Q3 2017. Trial requirement modified to require the concomitant use of oral and topical or phototherapy. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Exception made to retain the TB test requirement.	08.17	08.17
Added maximum dose allowance for PsA with PsO under the PsA diagnosis for clarity. Already reflected under PsO indication, therefore change is not significant	12.17	
2Q 2018 annual review: policies combined for HIM and Medicaid lines of business; HIM: modified trial and failure to require both Enbrel and Humira for PsA and AS, modified requirements for dose increase to 300 mg for PsA to require trial and failure of at least 3 consecutive months on 150 mg dose or evidence of coexistent PsO; Medicaid and HIM: removed specific diagnosis requirements for	02.27.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
PsO, removed trial and failure of phototherapy and topical therapy for PsO, removed TB testing for all indications; references reviewed and updated.		
4Q 2018 annual review: allowed bypassing conventional DMARDs for axial PsA and required trial of NSAIDs; references reviewed and updated.	09.04.18	11.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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