

Clinical Policy: Secukinumab (Cosentyx)

Reference Number: CP.PHAR.261

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Line of Business: 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 patients 6 years and older 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)
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- Adults with moderate to severe hidradenitis suppurativa (HS)

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. Axial Spondyloarthritis (must meet all):**

1. Diagnosis of AS or nr-axSpA;
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 clinically significant adverse effects are experienced or all are contraindicated;
5. For AS, member meets ALL* of the following, each used for \geq 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c, *see Appendix D*):
 - a. Failure of one adalimumab product (e.g., *Hadlima*™, *Simlandi*®, *Yusimry*™, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
 - b. Failure of Taltz®;

- c. If member has not responded or is intolerant to one or more TNF blockers, failure of Xeljanz[®]/Xeljanz XR[®], unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
**Prior authorization may be required for adalimumab products, Xeljanz/Xeljanz XR, and Taltz*
- 6. For nr-axSpA: Failure of Taltz*, used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Taltz*
- 7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 8. Dose does not exceed one of the following (a or b):
 - a. SC: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks;
 - b. IV: 6 mg/kg at week 0, followed by maintenance dose 1.75 mg/kg every 4 weeks.

Approval duration: 6 months

B. Enthesitis-related Arthritis (must meet all):

- 1. Diagnosis of ERA;
- 2. Prescribed by or in consultation with a rheumatologist;
- 3. Age ≥ 4 years and < 18 years;
- 4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
- 5. Member meets one of the following (a or b):
 - a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
 - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of at least ONE conventional disease-modifying anti-rheumatic drug (e.g., sulfasalazine, leflunomide) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
- 6. If disease is polyarticular (≥ 5 joints ever involved), failure of Actemra[®], used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or both are contraindicated;
**Prior authorization may be required for Actemra*
- 7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
- 8. Dose does not exceed one of the following (a or b):
 - a. Weight > 15 kg and < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks;
 - b. Weight ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks.

Approval duration: 6 months

C. Plaque Psoriasis (must meet all):

1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
 - a. $\geq 3\%$ of total body surface area;
 - b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 6 years;
4. Member meets one of the following (a, b, or c):
 - a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
 - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
 - c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. For age ≥ 18 years, member meets ONE of the following, unless contraindicated or clinically significant adverse effects are experienced (a or b, *see Appendix D*):
 - a. Failure of a ≥ 3 consecutive month trial of one* adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*);
 - b. History of failure of two TNF blockers;
**Prior authorization may be required for adalimumab products*
6. Failure of a ≥ 3 consecutive month trial of Taltz*, unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Taltz*
7. Failure of a ≥ 3 consecutive month trial of one ustekinumab product (e.g. *Otulfi*[®], *Pyzchiva*[®] (branded), *Selarsdi*[™], *Steqeyma*[®], *Yesintek*[™] are preferred), unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required for ustekinumab products*
8. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
9. Dose does not exceed the following:
 - a. Age ≥ 18 years: 300 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks;
 - b. Age 6 to 17 years and weight < 50 kg: 75 mg at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 75 mg every 4 weeks;
 - c. Age 6 to 17 years and weight ≥ 50 kg: 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. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 2 years;

4. For members ≥ 18 years, failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d, *see Appendix D*):
 - a. One adalimumab product (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;
 - b. *Otezla*[®];
 - c. *Taltz*;
 - d. If member has not responded or is intolerant to one or more TNF blockers, *Xeljanz/Xeljanz XR*, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

**Prior authorization may be required for adalimumab products, Otezla, Taltz, and Xeljanz/Xeljanz XR*
5. For members ≥ 6 years, failure of a ≥ 3 consecutive month trial of one ustekinumab product (e.g. *Otulf*[®], *Pyzchiva*[®] (branded), *Selarsdi*[™], *Steqeyma*[®], *Yesintek*[™] are preferred), unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required for ustekinumab products*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a or b):
 - a. PsA alone (i or ii):
 - i. Adults (1 or 2):
 - 1) SC: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks;
 - 2) IV: 6 mg/kg at week 0, followed by maintenance dose 1.75 mg/kg every 4 weeks;
 - ii. Pediatric (1 or 2):
 - 1) Weight > 15 kg and < 50 kg, SC: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks;
 - 2) Weight ≥ 50 kg, SC: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks;
 - b. PsA with PsO and ≥ 18 years: 300 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks.

Approval duration: 6 months

E. Hidradenitis Suppurativa (must meet all):

1. Diagnosis of HS;
2. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
3. Age ≥ 18 years;
4. Documentation of Hurley stage II or stage III (*see Appendix D*);
5. Failure of one adalimumab product* (e.g., *Hadlima*, *Simlandi*, *Yusimry*, *adalimumab-aaty*, *adalimumab-adaz*, *adalimumab-adbm*, and *adalimumab-fkjp* are preferred), unless the member has had a history of failure of two TNF blockers;

**Prior authorization may be required for adalimumab products*

6. Failure of at least TWO of the following, each tried for ≥ 3 consecutive months from different therapeutic classes, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:
 - a. Systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin);
 - b. Oral retinoids (e.g., acitretin, isotretinoin);
 - c. Hormonal treatment (e.g., estrogen-containing combined oral contraceptives, spironolactone);
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. 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

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member meets one of the following (a or b):
 - a. For HS: At least a 25% reduction in inflammatory nodules and abscesses;
 - b. For all other indications: Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);

4. If request is for a dose increase, new dose does not exceed one of the following (a, b, c, d, or e):
 - a. PsO alone (i, ii, or iii):
 - i. Age \geq 18 years: 300 mg every 4 weeks;
 - ii. Age 6 to 17 years and weight $<$ 50 kg: 75 mg every 4 weeks;
 - iii. Age 6 to 17 years and weight \geq 50 kg: 150 mg every 4 weeks;
 - b. PsA (i or ii):
 - i. Adults (1, 2, or 3):
 - 1) IV: 1.75 mg/kg every 4 weeks;
 - 2) SC: 150 mg every 4 weeks;
 - 3) SC: 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;
 - ii. Pediatric (1 or 2):
 - 1) Weight $>$ 15 kg and $<$ 50 kg, SC: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks;
 - 2) Weight \geq 50 kg, SC: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks;
 - c. AS, nr-axSpA (i, ii, or iii):
 - i. IV: 1.75 mg/kg every 4 weeks;
 - ii. SC: 150 mg every 4 weeks;
 - iii. SC: For AS only: 300 mg every 4 weeks, if documentation supports inadequate response to a \geq 3 consecutive month trial of 150 mg every 4 weeks;
 - d. ERA (i or ii):
 - i. Weight $>$ 15 kg and $<$ 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks;
 - ii. Weight \geq 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks;
 - e. HS (i or ii):
 - i. 300 mg every 4 weeks;
 - ii. 300 mg every 2 weeks, if documentation supports inadequate response to 300 mg every 4 weeks.

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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 – CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia[®], Enbrel[®], Humira[®] and its biosimilars, Remicade[®] and its biosimilars, Simponi[®]], interleukin agents [e.g., Actemra[®] (IL-6RA) and its biosimilars, Arcalyst[®] (IL-1 blocker), Bimzelx[®] (IL-17A and F antagonist), Cosentyx[®] (IL-17A inhibitor), Ilaris[®] (IL-1 blocker), Ilumya[™] (IL-23 inhibitor), Kevzara[®] (IL-6RA), Kineret[®] (IL-1RA), Omvoh[™] (IL-23 antagonist), Siliq[™] (IL-17RA), Skyrizi[™] (IL-23 inhibitor), Spevigo[®] (IL-36 antagonist), Stelara[®] (IL-12/23 inhibitor) and its biosimilars, Taltz[®] (IL-17A inhibitor), Tremfya[®] (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo[™], Olumiant[™], Rinvoq[™], Xeljanz[®]/Xeljanz[®] XR,], anti-CD20 monoclonal antibodies [Rituxan[®] and its biosimilars], selective co-stimulation modulators [Orencia[®]], integrin receptor antagonists [Entyvio[®]], tyrosine kinase 2 inhibitors [Sotyktu[™]], and sphingosine 1-phosphate receptor modulator [Velsipity[™]] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis	MTX: methotrexate
ERA: enthesitis-related arthritis	nr-axSpA: non-radiographic axial spondyloarthritis
FDA: Food and Drug Administration	NSAID: non-steroidal anti-inflammatory drug
HS: Hidradenitis suppurativa	PsA: psoriatic arthritis
IL-17A: interleukin-17A	PsO: plaque psoriasis
ILAR: International League of Associations for Rheumatology	
JAKi: Janus kinase inhibitors	

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	4 mg/kg/day
clindamycin (Cleocin [®]) + rifampin (Rifadin [®])	HS* clindamycin 300 mg PO BID and rifampin 300 mg PO BID	clindamycin: 600 mg/day rifampin: 600 mg/day
doxycycline (Acticlate [®])	HS* 50 – 100 mg PO BID	300 mg/day
Hormonal agents (e.g., estrogen- containing combined oral contraceptives, spironolactone)	HS varies	varies
Isotretinoin (Absorica [®] , Amnesteem [®] , Claravis [®] , Myorisan [®] , Zenatane [®])	HS varies	varies
leflunomide (Arava [®])	ERA Weight < 20 kg: 10 mg every other day Weight 20 - 40 kg: 10 mg/day Weight > 40 kg: 20 mg/day	20 mg/day
methotrexate (Rheumatrex [®])	PsO 10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week ERA 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
minocycline (Minocin [®])	HS* 50 – 100 mg PO BID	200 mg/day
sulfasalazine (Azulfidine [®])	ERA 30 to 50 mg/kg/day PO, given in 2 divided doses	2 g/day
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	AS, nr-axSpA, ERA Varies	Varies
Actemra [®] (tocilizumab)	PJIA (includes ERA with polyarticular disease) • Weight < 30 kg: 10 mg/kg IV every 4 weeks or 162 mg SC every 3 weeks	IV: 10 mg/kg every 4 weeks SC: 162 mg every 2 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<ul style="list-style-type: none"> Weight \geq 30 kg: 8 mg/kg IV every 4 weeks or 162 mg SC every 2 weeks <i>See Appendix E for dose rounding guidelines</i>	
Cimzia [®] (certolizumab)	nr-axSpA <u>Initial dose:</u> 400 mg SC at 0, 2, and 4 weeks <u>Maintenance dose:</u> 200 mg SC every other week (or 400 mg SC every 4 weeks)	400 mg every 4 weeks
Hadlima (adalimumab-bwwd), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma [®]), adalimumab-adaz (Hyrimoz [®]), adalimumab-fkjp (Hulio [®]), adalimumab-adbm (Cyltezo [®])	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 HS <u>Initial dose:</u> 160 mg SC on day 1, then 80 mg SC on Day 15 <u>Maintenance dose:</u> 40 mg SC every week or 80 mg SC every other week starting on Day 29	AS, PsA, PsO: 40 mg every other week HS: 40 mg/week
Otezla [®] (apremilast)	PsA <u>Initial dose:</u> Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM <u>Maintenance dose:</u> Day 6 and thereafter: 30 mg PO BID	60 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<p>Otulf[®] (ustekinumab-aauz), Pyzchiva[®] (ustekinumab-ttwe), Selarsdi[™] (ustekinumab-aekn), Steqeyma[®] (ustekinumab-stba), Yesintek[™] (ustekinumab-kfce)</p>	<p>PsO Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks</p> <p><i>Adult:</i> Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg</p> <p><i>Pediatrics (age 6 years to 17 years):</i> Otulf[®], Pyzchiva[®], Yesintek[™]: Weight < 60 kg: 0.75 mg/kg</p> <p>Otulf[®], Pyzchiva[®], Selarsdi[™], Steqeyma[®], Yesintek[™]: Weight 60 to 100 kg: 45 mg Weight > 100 kg: 90 mg</p> <p>PsA Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks</p> <p><i>Adult:</i> 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks</p> <p><i>Pediatrics (age 6 years to 17 years):</i> Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter</p> <p>Otulf[®], Pyzchiva[®], Yesintek[™]: Weight < 60 kg: 0.75 mg/kg</p> <p>Otulf[®], Pyzchiva[®], Selarsdi[™], Steqeyma[®], Yesintek[™]: Weight ≥ 60 kg: 45 mg</p>	<p>PsO: 90 every 12 weeks</p> <p>PsA: 45 mg every 12 weeks</p>
<p>Taltz[®] (ixekizumab)</p>	<p>AS, nr-axSpA, PsA <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0 <u>Maintenance dose:</u> 80 mg SC every 4 weeks</p>	<p>80 mg every 4 weeks</p>

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	PsO <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 <u>Maintenance dose:</u> 80 mg SC every 4 weeks	
Xeljanz [®] (tofacitinib)	AS, PsA 5 mg PO BID	10 mg/day
Xeljanz XR [®] (tofacitinib extended-release)	AS, PsA 11 mg PO QD	11 mg/day

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 D: 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
- ERA: Current International League of Associations for Rheumatology (ILAR) classification criteria divide JIA into 7 mutually exclusive categories defined by the number of joints involved, presence or absence of extraarticular manifestations, and presence or absence of additional markers including rheumatoid factor (RF) and HLA-B27. While the current ILAR classification criteria have been useful for identifying homogeneous groups of patients for research, more recent data suggest that these categories may not entirely reflect the underlying genetic and clinical heterogeneity of the disease or be relevant for guiding treatment decisions. According to the 2019 American

College of Rheumatology, current treatment guideline focuses treatment approaches based on broad clinical phenotypes rather than ILAR categories.

- TNF blockers:
 - Etanercept (Enbrel[®]), adalimumab (Humira[®]) and its biosimilars, infliximab (Remicade[®]) and its biosimilars (Avsola[™], Renflexis[™], Inflectra[®]), certolizumab pegol (Cimzia[®]), and golimumab (Simponi[®], Simponi Aria[®]).
- Hidradenitis suppurativa:
 - HS is sometimes referred to as: "acne inversa, acne conglobata, apocrine acne, apocrinitis, Fox-den disease, hidradenitis axillaris, HS, pyoderma sinifica fistulans, Velpeau's disease, and Verneuil's disease."
 - In HS, Hurley stages are used to determine severity of disease. Hurley stage II indicates moderate disease, and is characterized by recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions. Hurley stage III indicates severe disease, and is characterized by diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsO (with or without PsA)	<p>Adults: 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)</p> <p>Pediatric patients age 6 to 17 years and weight < 50 kg (PsO only): 75 mg SC at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 75 mg every 4 weeks</p> <p>Pediatric patients age 6 to 17 years and weight ≥ 50 kg (PsO only): 150 mg SC at weeks 0, 1, 2, 3 and 4, followed by maintenance dose of 150 mg every 4 weeks</p>	<p>Adults: 300 mg every 4 weeks</p> <p>Pediatric patients: 150 mg every 4 weeks</p>
PsA	<p><u>Adults:</u></p> <p><i>Subcutaneous:</i></p> <ul style="list-style-type: none"> • 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. <p><i>Intravenous infusion:</i></p> <ul style="list-style-type: none"> • With loading dose: 6 mg/kg IV at week 0, followed by 1.75 mg/kg IV every 4 weeks. • Without loading dose: 1.75 mg/kg IV every 4 weeks. 	<p>Adults: 300 mg every 4 weeks</p> <p>Pediatric patients: 150 mg every 4 weeks</p>

Indication	Dosing Regimen	Maximum Dose
	<u>Pediatric:</u> <i>Subcutaneous:</i> Pediatric patients age 2 to 17 years and weight ≥ 15 kg and < 50 kg: 75 mg SC at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks. Pediatric patients age 2 to 17 years old and weight ≥ 50 kg: 150 mg SC at weeks 0, 1, 2, 3, and 4, followed by a maintenance dose of 150 mg every 4 weeks.	
AS, nr-axSpA	<i>Subcutaneous:</i> <ul style="list-style-type: none"> • 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. • For AS only: if a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg. <i>Intravenous infusion:</i> <ul style="list-style-type: none"> • With loading dose: 6 mg/kg IV at week 0, followed by 1.75 mg/kg IV every 4 weeks. • Without loading dose: 1.75 mg/kg IV every 4 weeks. 	300 mg every 4 weeks <u>nr-axSpA (SC):</u> 150 mg every 4 weeks (after loading doses)
ERA	<ul style="list-style-type: none"> • Weight > 15 kg and < 50 kg: 75 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 75 mg every 4 weeks • Weight ≥ 50 kg: 150 mg at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 150 mg every 4 weeks 	Weight < 50 kg: 75 mg every 4 weeks (after loading doses) Weight ≥ 50 kg: 150 mg every 4 weeks (after loading doses)
HS	300 mg SC at weeks 0, 1, 2, 3, and 4, followed by maintenance dose of 300 mg every 4 weeks Consider increasing the dosage to 300 mg every 2 weeks if patient does not adequately respond	300 mg every 2 weeks

VI. Product Availability

- Single-dose UnoReady pen: 300 mg/2 mL
- Single-dose Sensoready[®] pen: 150 mg/mL
- Single-dose prefilled syringe: 75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL
- Single-dose vial (for IV infusion): 125 mg/5 mL

VII. References

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPSC Codes	Description
J3247	Injection, secukinumab, intravenous, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2021 annual review: added additional criteria related to diagnosis of moderate-to-severe PsO per 2019 AAD/NPF guidelines specifying at least 3% BSA involvement or involvement of areas that severely impact daily function; added combination of bDMARDs under Section III; references reviewed and updated.	02.23.21	05.21
RT4: updated PsO age requirement from ≥ 18 years to ≥ 6 years per FDA pediatric expansion; added new 75 mg/0.5 mL prefilled syringe for pediatric patients.	06.04.21	
Per SDC and prior clinical guidance, for AS, revised redirection requirement from two among the preferred to all of the preferred; for PsA removed Simponi as a redirect option and modified to require a trial of all; for Xeljanz redirection requirements added bypass for members with cardiovascular risk and qualified redirection to apply only for member that has not responded or is intolerant to one or more TNF blockers; added Legacy WellCare line of business to policy (WCG.CP.PHAR.261 to be retired).	08.25.21	11.21
2Q 2022 annual review: for AS, added redirection to Xeljanz if failed prior TNF blocker per August SDC and updated FDA labeling; RT4: applied FDA-approved pediatric use extension down to 2 years of age for active PsA; for PsA, modified redirection to apply for age 18 or older; added newly approved indication for active ERA; for PsO, allowed phototherapy as alternative to systemic conventional DMARD if contraindicated or clinically significant adverse effects are experienced; removed separate legacy wellcare approval durations; reiterated requirement against combination use with a bDMARD or JAKi from Section III to Sections I and II; references reviewed and updated.	02.18.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.13.22	
2Q 2023 annual review: updated off-label dosing in Appendix B; for AS and PsA, added TNFi criteria to allow bypass if member has had history of failure of two TNF blockers; references reviewed and updated.	02.10.23	05.23

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: added new dosage forms (UnoReady Pen and 300 mg/2 mL dose of pre-filled syringe) to policy.	05.25.23	
Per July SDC: for AS, removed criteria requiring use of Enbrel and Cimzia; for PsA and ERA, removed criteria requiring use of Enbrel; for AS, PsO, PsA, added criteria requiring use of one adalimumab product and stating Yusimry, Hadlima, unbranded adalimumab-fkjp, and unbranded adalimumab-adaz as preferred; for nr-axSpA, removed redirection to Cimzia; updated Appendix B with relevant therapeutic alternatives.	07.25.23	
RT4: added new dosage form single-dose vial 125 mg/ 5 mL for intravenous infusion; added IV specific dosing for AS, nr-axSpA and PsA; added Tofidence to section III.B.	10.30.23	
Per December SDC, added adalimumab-adbm to listed examples of preferred adalimumab products. RT4: added newly approved HS indication to criteria; added Wezlana to section III.B; updated HCPCS code description for J3590.	12.06.23	02.24
Added new HCPCS code [C9166] and removed HCPCS codes [C9399, J3590].	02.19.24	
2Q 2024 annual review: updated Appendix D with removal of PsA, AS, and nr-axSpA guideline supplemental information; added Bimzelx, Zymfentra, Omvoh, Tofidence, Sotyktu, and Velsipity to section III.B; references reviewed and updated.	01.25.24	05.24
Added HCPCS code [J3247] and removed code [C9166].	06.03.24	
Per June SDC: for AS, PsO, PsA, HS, added Simlandi to listed examples of preferred adalimumab products. Per SDC: for AS, PsO, PsA, HS, added unbranded adalimumab-aaty to listed examples of preferred adalimumab products.	07.23.24	08.24
2Q 2025 annual review: for ERA initial criteria, added statement disclaimer that prior authorization may be required for Actemra; for continued therapy section, removed “if new dosing regimen, approve for 6 months” for approval duration; updated section III.B with Spevigo and biosimilar verbiage; references reviewed and updated.	01.23.25	05.25
Per April SDC: for PsO and PsA, added criteria requiring use of one preferred Stelara biosimilar (Otulfi, Pyzchiva (branded), Selarsdi, Yesintek, and Steqeyma are preferred).	04.23.25	06.25

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

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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.

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