RxAdvance

Clinical Policy Title:	secukinumab
Policy Number:	RxA.733
Drug(s) Applied:	Cosentyx®
Original Policy Date:	4/18/2022
Last Review Date:	4/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Cosentyx® is a human interleukin-17A antagonist 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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
secukinumab (Cosentyx®)	PsA	<u>With loading dose:</u> 150 mg subcutaneously at week 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks <u>Without loading dose:</u> 150 mg subcutaneously every 4 weeks If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg every 4 weeks. <u>Pediatric Patients 2 years and older:</u> Recommended dosage is administered by subcutaneously injection at weeks 0,1 ,2,3, and 4 and every 4 weeks after: For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.	300 mg every 4 weeks
	AS, nr-axSpA	<u>With loading dose:</u> 150 mg subcutaneously at weeks 0, 1, 2, 3, and 4, followed by 150 mg subcutaneously every 4 weeks thereafter <u>Without loading dose:</u> 150 mg subcutaneously every 4 weeks If the patient continues to have active ankylosing	AS: 300mg every 4 weeks Nr-axSpA: 150 mg every 4 weeks

Dosing Information			
Drug Name	**Indication**	**Dosing Regimen**	**Maximum Dose**
		spondylitis: 300 mg every 4 weeks can be considered	
	Enthesitis-Related Arthritis (ERA)	Recommended dosage is administered by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. For patients weighing ≥ 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.	Subcutaneous:150 mg at week 0,1,2,3 and 4 and every week thereafter
	Plaque Psoriasis	Adults: Recommended dosage is 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. For some patients, a dose of 150 mg may be acceptable. Children and Adolescents 6 to 17 years weighing 50 kg or more: 150 mg subcutaneously at weeks 0, 1, 2, 3, and 4. Then give 150 mg subcutaneously every 4 weeks. Children and Adolescents 6 to 17 years weighing less than 50 kg: 75 mg subcutaneously at weeks 0, 1, 2, 3, and 4. Then give 75 mg subcutaneously every 4 weeks	Age ≥ 18 years: 300 mg/dose subcutaneously Age 6 to 17 years old weighing 50 kg or more: 150 mg/dose subcutaneously. Age 6 to 17 years weighing less than 50 kg: 75 mg/dose subcutaneously.

Dosage Forms

- Injection: 150 mg/mL solution in a single-dose Sensoready® pen and in a single-dose prefilled syringe
- Injection: 75 mg/0.5 mL solution in a single-dose prefilled syringe (for pediatric patients)
- For Injection: 150 mg, lyophilized powder in a single-dose vial for reconstitution

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Ankylosing Spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Trial and failure of at least two (2) non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
5. For Ankylosing Spondylitis, member meets both (a and b):

a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Simponi® or Simponi Aria® unless contraindicated or clinically significant adverse effects are experienced;
*Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.
b. Trial and failure of at least one (1) of the following agents: Xeljanz®/XR or Taltz® unless contraindicated or clinically significant adverse effects are experienced;

6. For non-radiographic axial spondyloarthritis: Trial and failure of both Cimzia® and Taltz®, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 300 mg every 4 weeks for AS and 150 mg every 4 weeks for Nr-axSpA.

Approval duration
Commercial: 12 months
Medicaid: 12 months

B. Plaque Psoriasis (must meet all):
1. Diagnosis of Plaque Psoriasis (PsO);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age ≥ 6 years;
4. Trial and failure of ≥ 3 months of at least one (1) conventional systemic therapy (methotrexate [MTX], cyclosporin, acitretin) or phototherapy (psoralen plus ultraviolet A light [PUVA]) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
*Exception: If one biologic DMARD that is FDA-approved for plaque psoriasis has been previously tried, then trial of a conventional systemic agent or phototherapy is not required;
5. Member meets both (a and b);
   a. Trial and failure of at least three (3) of the following agents: Humira®, Cimzia®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.
   b. Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed one of the following: (a, b or c)
   a. Age ≥ 18 years :300 mg/dose subcutaneously every 4 weeks.
   b. Age 6 to 17 years old weighing 50 kg or more: 150 mg/dose subcutaneously every 4 weeks.
   c. Age 6 to 17 years old weighing less than 50 kg: 75 mg/dose subcutaneously every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

C. Psoriatic Arthritis (must meet all):
1. Diagnosis of Psoriatic Arthritis (PsA);
2. Prescribed by or in consultation with a dermatologist or a rheumatologist;
3. Age ≥ 2 years;
4. Members meets both (a and b):
   a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, Skyrizi®, Tremfya®, Stelara® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has

previously been tried and failed, trial of a third TNF inhibitor is not required.

b. Trial and failure of both Orencia® and Taltz® unless contraindicated or clinically significant adverse effects are experienced;

5. Dose does not exceed 300 mg every 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

D. Enthesitis-related Arthritis (ERA) (must meet all):

1. Diagnosis of Enthesitis-related Arthritis **(**ERA);
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 4 years;
4. Member meets one of the following (a or b):
   a. Trial and failure of corticosteroids (oral or intraarticular steroid e.g. triamcinolone hexacetonide) unless contraindicated or clinically significant adverse effects experienced;
   b. Trail and failure of ≥ 3 months of at least one (1) conventional systemic therapy (e.g, sulfasalazine, methotrexate) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   *Exception: If one biologic DMARD that is FDA-approved for crohn's disease has been previously tried, then trial of a conventional systemic agent is not required;
5. Trial and failure of for ≥ 3 months of Humira® unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 150 mg/dose subcutaneously.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Dose does not exceed 150 mg/dose subcutaneously for non-radiographic axial spondyloarthritis and enthesitis-related arthritis, for other indication: 300 mg/dose subcutaneously.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
PsA: Psoriatic arthritis
AS: Ankylosing spondylitis
nr-axSpA: non-radiographic axial spondyloarthritis
ERA: Enthesitis-related arthritis
NSAIDs: Non-Steroidal Anti-Inflammatory Drugs
DMARDs: Disease-Modifying Antirheumatic Drugs

TB: Tuberculosis
TNF: Tumor necrosis factor
PsO: Plaque Psoriasis
PUVA: psoralen plus ultraviolet A light

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin	**PsO:** 25 or 50 mg orally once daily	50 mg/day
cyclosporine (Sandimmune®, Neoral®)	**PsO:** 1 – 4 mg/kg/day orally divided twice daily	4 mg/kg/day
methotrexate	**PsO:** 10 – 25 mg/week orally or 2.5 mg orally every 12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	**AS, nr-axSpA:** Varies	Varies
Biologic DMARDs		
Humira®	**PsO**: Initial dose: 80 mg Maintenance dose: 40 mg subcutaneous every other week starting one week after initial dose **AS, PsA**: 40 mg subcutaneously every other week	40 mg every other week
infliximab (Remicade®), Renflexis®, Inflectra®, Avsola®	**PsA, PsO:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 8 weeks **AS:** Initial dose: 5 mg/kg intravenously at weeks 0, 2 and 6 Maintenance dose: 5 mg/kg intravenously every 6 weeks	PsA, PsO: 5 mg/kg every 8 weeks AS: 5 mg/kg every 6 weeks
Simponi Aria®	**AS** **PsA :** Initial dose: 2 mg/kg IV at weeks 0 and 4 Maintenance dose: 2 mg/kg intravenous every 8 weeks	AS PsA : 2 mg/kg every 8 weeks
Otezla®	**PsO** **PsA:** Initial dose: Day 1: 10 mg orally in morning Day 2: 10 mg orally in morning and 10 mg orally in evening	60 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Day 3: 10 mg orally in morning and 20 mg orally in evening Day 4: 20 mg orally in morning and 20 mg orally in evening Day 5: 20 mg orall in morning and 30 mg orally in evening Maintenance dose: Day 6 and thereafter: 30 mg orally twice daily	
Xeljanz® / Xeljanz® oral Solution, Xeljanz® XR	Xeljanz®: **PsA, AS**: 5 mg orally twice daily PsA: use in combination with nonbiologic disease-modifying antirheumatic drugs Xeljanz® XR: **PsA, AS**: 11 mg orally once daily	Xeljanz®: PsA AS: 10 mg/day Xeljanz® / Xeljanz® oral Solution: 5 mg or 5 ml twice daily Xeljanz® XR: 11 mg/day
Cimzia®	**PsA, AS, nr-axSpA:** Initial dose: 400 mg subcutaneously at 0, 2, and 4 weeks. Maintenance dose: 200 mg subcutaneously every other week (or 400 mg subcutaneous every 4 weeks) **PsO:** 400 mg subcutaneously every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg subcutaneously at 0, 2 and 4 weeks, followed by 200 mg subcutaneously every other week may be considered.	**RA, PsA, AS, nr-axSpA:** 400 mg every 4 weeks **PsO:** 400 mg every other week
Enbrel®	**PsA**: Adult: 50 mg once weekly with or without methotrexate (MTX) **AS:** 50 mg once weekly **PsO:** Adult PsO: 50 mg twice weekly for 3 months, followed by 50 mg once weekly Pediatric PsO: Weight < 63 kg: 0.8 mg/kg subcutaneously once weekly Weight ≥ 63 kg: 50 mg subcutaneously once weekly	Adults 50 mg/week subcutaneously. Induction therapy for psoriatic arthritis should not exceed 100 mg/week with no more than 50 mg/dose subcutaneously. **AS, PsO:** 50 mg/week
Ilumya®	**PsO:** Initial dose: 100 mg subcutaneous at weeks 0 and 4 Maintenance dose: 100 mg subcutaneous every 12 weeks Tildrakizumab should only be administered by a healthcare professional.	100 mg every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Orencia®	**PsA:** Intravenous: weight-based dose at weeks 0, 2, and 4, followed by every 4 weeks Weight < 60 kg: 500 mg per dose Weight 60 to 100 kg: 750 mg per dose Weight > 100 kg: 1,000 mg per dose Subcutaneous: 125 mg once weekly	**PsA:** Intravenous: 1,000 mg every 4 weeks Subcutaneous: 125 mg/week
Rinvoq®	**PsA:** 15 mg orally once daily Can be used as monotherapy or in combination with methotrexate or other non biologic DMARDs. *For use in adults who have had an inadequate response or intolerance to one or more TNF blockers	15 mg/day
Siliq®	**PsO:** Initial dose: 210 mg subcutaneous at weeks 0, 1, and 2 Maintenance dose: 210 mg subcutaneous every 2 weeks	210 mg every 2 weeks
Simponi®	**AS, PsA:** 50 mg subcutaneous once monthly	50 mg/month
Tremfya®	**PsO, PsA:** Initial dose: 100 mg subcutaneous at weeks 0 and 4 Maintenance dose: 100 mg subcutaneous every 8 weeks Can be used alone or in combination with conventional DMARD e.g. methotrexate	100 mg every 8 weeks
Taltz®	**PsO:** Adult Plaque Psoriasis: Recommended dose is 160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks Pediatric Plaque Psoriasis(age 6 years or older): For patients weighing greater than 50 kg:160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks. For patients weighing 25-50 kg: 80 mg subcutaneoulsy at Week 0, followed by 40 mg every 4 weeks. For patients weighing less than 25 kg:40 mg subcutaneously at Week 0, followed by 20 mg every 4 weeks **PsA, AS:** Initial dose: 160 mg (two 80 mg injections) subcutaneous Maintenance dose: 80 mg subcutaneous every 4 weeks.	**PsO:** 80 mg every 4 weeks **nraxSpA, PsA, AS:** 80 mg every 4 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Skyrizi®	**PsO:** 150 mg subcutaneous at weeks 0, 4, and every 12 weeks thereafter	150 mg/12 Weeks
Stelara®	**PsO:** Weight based dosing subcutaneous at weeks 0 and 4, followed by maintenance dose every 12 weeks Adult: Weight ≤ 100 kg: 45 mg (some patients may require doses of 90 mg or maintenance dosing of every 8 weeks) Weight > 100 kg: 90 mg (some patients may require maintenance dosing of every 8 weeks) Pediatrics (Age 6 years and older): Weight < 60 kg: 0.75 mg/kg Weight ≥ 60 to ≤100 kg: 45 mg Weight > 100kg: 90 mg **PsA:** 45 mg subcutaneous at weeks 0 and 4, followed by 45 mg every 12 weeks	**PsO:** 90 mg every 8 weeks **PsA:** 45 mg every 12 weeks

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Serious hypersensitivity to secukinumab or any excipients.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Ankylosing Spondylitis: Several AS treatment guidelines call for a trial of 2 or 3 NSAIDs prior to use of an anti- TNF agent. A two-year trial showed that continuous NSAID use reduced radiographic progression of AS versus on demand use of NSAID.
- Psoriatic Arthritis: According to the 2019 American College of Rheumatology TNF inhibitors is recommended over other biologics for use in treatment-naïve patients with psoriatic arthritis, and in those who were previously treated with an oral therapy.

References

1. Cosentyx® Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2021. Available at: https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/cosentyx.pdf. Accessed February 09, 2022.
2. Boulos P, Dougados M, MacLeod SM, et al. Pharmacological Treatment of Ankylosing Spondylitis. Drugs. 2005; 65: 2111-2127. Available at: https://pubmed.ncbi.nlm.nih.gov/16225367/. Accessed February 09, 2022.

3. Braun J, Davis J, Dougados M, et al. First update of the international ASAS consensus statement for the use of anti-TNF agents in patients with ankylosing spondylitis. Ann Rheum Dis. 2006; 65:316-320. Available at: https://pubmed.ncbi.nlm.nih.gov/16096329/. Accessed February 09, 2022.
4. Braun J, van den Berg R, Baraliako X, et al. 2010 Update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis 2011; 70:896-904. Available at: https://pubmed.ncbi.nlm.nih.gov/21540199/. Accessed February 09, 2022.
5. Menter A, Gottlieb A, Feldman SR, 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; 58:826-850. Available at: https://www.jaad.org/article/S0190-9622(08)00273-9/fulltext. Accessed February 09, 2022.
6. Menter A, Gottlieb A, Feldman, SR, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol May 2008; 58(5): 826-50. Available at: https://pubmed.ncbi.nlm.nih.gov/18423260/. Accessed February 09, 2022.
7. Menter A, Korman NF, Elmets CA, 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. 10.1016/j.jaad.2009.03.027. Available at: https://pubmed.ncbi.nlm.nih.gov/19493586/. Accessed February 09, 2022.
8. Menter A, Korman, NJ, Elmets CA, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol. 2009; 60:643-659. Available at: https://pubmed.ncbi.nlm.nih.gov/19217694/. Accessed February 09, 2022.
9. Ward M, Deodhar A, Akl E, 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. Available at: http://www.rheumatology.org. Accessed February 09, 2022.
10. van der Heijde D, Ramiro S, Landewe R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis. 2017; 76:978- 991. doi:10.1136/annrheumdis-2016-210770. Available at: https://pubmed.ncbi.nlm.nih.gov/28087505/. Accessed February 09, 2022.
11. Zochling J, van der Heijde D, Burgos-Vargas, R, et al. ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2006; 65:442-452. Available at: https://pubmed.ncbi.nlm.nih.gov/16126791/. Accessed February 09, 2022.
12. 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 2015; 0:1-12. doi:10.1136/annrheumdis-2015-208337. Available at: https://pubmed.ncbi.nlm.nih.gov/26644232/. Accessed February 09, 2022.
13. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. doi: 10.1002/art.40726. Available at: https://pubmed.ncbi.nlm.nih.gov/30499246/. Accessed October 22, 2021.
14. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed February 09, 2022.
15. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 09, 2022.
16. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 09, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Biologic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Biologics_DMARDs.	01/05/2022	4/18/2022
Drug specific policy for Cosentyx was created based on RxA.592.Biologics_DMARDs: 1. Dosing information for Cosentyx® was updated to include pediatric dosing for psoriatic arthritis. 2. Dosing information for Cosentyx® updated to include indication and dosing information for Enthesitis-related Arthritis (ERA). 3. Dosing Information, Dosing Regimen, Cosentyx: Updated dosing information from Pediatric Patients 6 years of age and older to Children and Adolescents 6 to 17 years. 4. Initial Approval Criteria, I.A.5: Updated to remove prior trial and failure criteria "Failure of two (2) of the following: Humira®, Cimzia®, Inflectra®, Renflexis™, Simponi®, Simponi Aria®, Xeljanz®, Xeljanz® XR and Taltz®; each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced". 5. Initial Approval Criteria, I.A.5: Updated to include new trial and failure criteria (a and b): a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Simponi® or Simponi Aria® unless contraindicated or clinically significant adverse effects are experienced; *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required. b. Trial and failure of at least one (1) of the following agents: Xeljanz®/XR or Taltz® unless contraindicated or clinically significant adverse effects are experienced; 6. Initial Approval Criteria, 1.B.4: Updated trial and failure criteria to rephrase and	02/09/2022	4/18/2022

include phototherapy (psoralen plus ultraviolet A light [PUVA]).

7. Initial Approval Criteria, I.B.5: Updated to include new trial and failure criteria (a and b):
   a. Trial and failure of at least three (3) of the following agents: Humira®, Cimzia®, Skyrizi®, Tremfya® or Stelara® unless contraindicated or clinically significant adverse effects are experienced;

   *Exception: If a total of two TNF inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required.

   b. Trial and failure of Taltz® unless contraindicated or clinically significant adverse effects are experienced.
8. Initial Approval Criteria, I.B.6: Updated dosing criteria from general dosing to age and weight-based dosing.
9. Initial Approval Criteria I.C.3 from Age ≥ 18 years to Age ≥ 2 years.
10. Initial Approval Criteria, I.C.4: Updated to remove prior trial and failure criteria "Failure of a trial of two (2) of the following, each used for ≥ 3 months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia®, Humira®, Inflectra®, Otezla®, Renflexis™, Rinvoq™, Simponi®, Simponi Aria®, Stelara®, Taltz®, or Xeljanz®/ Xeljanz XR®."
11. Initial Approval Criteria, I.C.4: Updated to include new trial and failure criteria (a and b):
    a. Trial and failure of at least two (2) of the following agents: Humira®, Cimzia®, Rinvoq®, Simponi®/ Simponi Aria®, Skyrizi®, Tremfya®, Stelara® or Xeljanz®/ XR unless contraindicated or clinically significant adverse effects are experienced;

    *Exception: If a total of two TNF

inhibitors (Humira®, Cimzia®, Simponi®, Simponi Aria®, Enbrel®) has previously been tried and failed, trial of a third TNF inhibitor is not required. b. Trial and failure of both Orencia® and Taltz® unless contraindicated or clinically significant adverse effects are experienced; 12. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Enthesitis-related Arthritis. 13. Appendix A: Updated to include abbreviations PUVA. 14. Appendix B, Drug Name: Updated to remove discontinued brand-name therapeutic alternative Soriatane®. 15. Appendix B, Drug Name: Updated to include brand-name therapeutic alternative of other biological DMARDs. 16. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 17. Appendix D, General Information: Updated to remove information regarding: (a, b, c and d) a. Safety information regarding Cosentyx use. b. Definition of failure of MTX or DMARDs; c. Examples of positive response to therapy. 18. References were reviewed and updated.		