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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical products	**Original Policy Date:**	February 13, 2015
Subject:	Cosentyx	**Page:**	1 of 12

Last Review Date: March 8, 2024

Cosentyx

Description

Cosentyx (secukinumab)

Background
Cosentyx (secukinumab) is a human interleukin-17A (IL-17A) antagonist that helps regulate inflammation associated with plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and enthesitis-related arthritis (ERA). Cosentyx binds to IL-17A and prevents it from binding to its receptor inhibiting its ability to trigger an inflammatory response (1).

Regulatory Status
FDA-approved indications: Cosentyx is a human interleukin-17A antagonist indicated for the treatment of: (1)

1. Moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis (PsA) in patients 2 years of age and older
3. Adults with active ankylosing spondylitis (AS)
4. Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
5. Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
6. Adults with moderate to severe hidradenitis suppurativa (HS)

Evaluate patients for tuberculosis infection prior to initiating treatment with Cosentyx. Do not administer Cosentyx to patients with active tuberculosis. Initiate treatment of latent tuberculosis

prior to administering Cosentyx. Consider anti-tuberculosis therapy prior to initiation of Cosentyx in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Cosentyx should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1).

Serious allergic reactions have been reported with the use of Cosentyx. Cosentyx affects the immune system, thus patients may have a greater risk of getting an infection. Caution should be exercised when considering the use of Cosentyx in patients with a chronic infection or history of recurrent infection, and in patients with active Crohn's disease. Patients treated with Cosentyx should not receive live vaccines (1).

Cosentyx may cause inflammatory bowel disease. Caution should be exercised when prescribing Cosentyx to patients with inflammatory bowel disease, and all patients should be evaluated for signs and symptoms of inflammatory bowel disease (1).

The safety and effectiveness of Cosentyx in pediatric patients less than 6 years of age with plaque psoriasis have not been established. The safety and effectiveness of Cosentyx in pediatric patients less than 2 years of age with psoriatic arthritis have not been established. The safety and effectiveness of Cosentyx in pediatric patients less than 4 years of age with enthesitis-related arthritis have not been established. The safety and effectiveness of Cosentyx in pediatric patients less than 18 years of age with ankylosing spondylitis, non-radiographic axial spondyloarthritis, or hidradenitis suppurativa have not been established (1).

Related policies
Siliq, Taltz

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cosentyx may be considered **medically necessary** if the conditions indicated below are met.

Cosentyx may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe plaque psoriasis (PsO)
    a. 6 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
        i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate response, intolerance, or contraindication to the other treatment option
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 300 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Active psoriatic arthritis (PsA)
    a. 2 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion (Age 18 and older only): 1.75 mg/kg every 4 weeks
        ii. Subcutaneous administration: 300 mg every 4 weeks
    d. **Age 18+ only**: Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Active ankylosing spondylitis (AS)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
    c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1.75 mg/kg every 4 weeks
        ii. Subcutaneous administration: 300 mg every 4 weeks

d. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Active non-radiographic axial spondyloarthritis (nr-axSpA)
   a. 18 years of age or older
   b. Patient has objective signs of inflammation
   c. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
   d. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. IV infusion: 1.75 mg/kg every 4 weeks
      ii. Subcutaneous administration: 150 mg every 4 weeks
   e. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Active enthesitis-related arthritis (ERA)
   a. 4 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. Subcutaneous administration: 150 mg every 4 weeks

6. Hidradenitis Suppurativa (HS)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. Subcutaneous administration: 300 mg every 2 weeks

AND ALL of the following for **ALL** diagnoses:

1. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
2. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
3. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
4. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Plaque psoriasis (PsO)
   a. 6 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. Subcutaneous administration: 300 mg every 4 weeks
   c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Psoriatic arthritis (PsA)
   a. 2 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. IV infusion (Age 18 and older only): 1.75 mg/kg every 4 weeks
      ii. Subcutaneous administration: 300 mg every 4 weeks
   c. **Age 18+ only**: Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Ankylosing spondylitis (AS)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. IV infusion: 1.75 mg/kg every 4 weeks
      ii. Subcutaneous administration: 300 mg every 4 weeks
   c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Non-radiographic axial spondyloarthritis (nr-axSpA)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. IV infusion: 1.75 mg/kg every 4 weeks
        ii. Subcutaneous administration: 150 mg every 4 weeks
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Enthesitis-related arthritis (ERA)
    a. 4 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 150 mg every 4 weeks

6. Hidradenitis Suppurativa (HS)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 300 mg every 2 weeks

AND ALL of the following for **ALL** diagnoses:
1. Condition has improved or stabilized with therapy
2. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
3. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity

Ankylosing spondylitis (AS)	150 mg SC syringe 300 mg SC syringe 300 mg carton (2x150 mg) SC syringe	17 units per 365 days (Loading dose of 150 mg at Weeks 0, 1, 2, 3, 4 then 150mg or 300mg every 4 weeks)
	125 mg/5 mL IV vial	(Loading dose of 6 mg/kg at Week 0, then 1.75 mg/kg every 4 weeks)
Hidradenitis suppurativa (HS)	300 mg SC syringe 300 mg carton (2x150 mg) SC syringe	29 units per 365 days (Loading dose of 300 mg at Weeks 0, 1, 2, 3, 4 then 300 mg every 2-4 weeks)
Plaque psoriasis (PsO) **Age 18+ only**	150 mg SC syringe 300 mg SC syringe 300 mg carton (2x150 mg) SC syringe	17 units per 365 days (Loading dose of 150 mg or 300 mg at Weeks 0, 1, 2, 3, 4 then 150mg or 300mg every 4 weeks)
Psoriatic arthritis (PsA) **Age 18+ only**	150 mg SC syringe 300 mg SC syringe 300 mg carton (2x150 mg) SC syringe	17 units per 365 days (Loading dose of 150 mg or 300 mg at Weeks 0, 1, 2, 3, 4 then 150mg or 300mg every 4 weeks)
	125 mg/5 mL IV vial	(Loading dose of 6 mg/kg at Week 0, then 1.75 mg/kg every 4 weeks)
Enthesitis-related arthritis (ERA) Psoriatic arthritis (PsA) **Age 2 - 17 only** Plaque psoriasis (PsO) **Age 6 - 17 only**	75 mg SC syringe 150 mg SC syringe	17 units per 365 days (Loading dose of 75 mg or 150 mg at Weeks 0, 1, 2, 3, 4 then 75 mg or 150 mg every 4 weeks)
Non-radiographic axial spondyloarthritis (nr-axSpA)	150 mg SC syringe	17 units per 365 days (Loading dose of 150 mg at Weeks 0, 1, 2, 3, 4 then 150 mg every 4 weeks)
	125 mg/5 mL IV vial	(Loading dose of 6 mg/kg at Week 0, then 1.75 mg/kg every 4 weeks)

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Ankylosing spondylitis (AS)	150 mg SC syringe 300 mg SC syringe 300 mg carton (2 of the 150 mg) SC syringe	3 units per 84 days
	125 mg/5 mL IV vial	1.75 mg/kg every 4 weeks
Hidradenitis suppurativa (HS)	300 mg SC syringe 300 mg carton (2 of the 150 mg) SC syringe	6 units per 84 days
Plaque psoriasis (PsO) **Age 18+ only**	150 mg 300 mg 300 mg carton (2 of the 150mg)	3 units per 84 days
Psoriatic arthritis (PsA) **Age 18+ only**	150 mg SC syringe 300 mg SC syringe	3 units per 84 days

	300 mg carton (2 of the 150 mg) SC syringe	
	125 mg/5 mL IV vial	1.75 mg/kg every 4 weeks
Enthesitis-related arthritis (ERA)	75 mg SC syringe 150 mg SC syringe	3 units per 84 days
Psoriatic arthritis (PsA) **Age 2 - 17 only**		
Plaque psoriasis (PsO) **Age 6 - 17 only**		
Non-radiographic axial spondyloarthritis (nr-axSpA)	150 mg SC syringe	3 units per 84 days
	125 mg/5 mL IV vial	1.75 mg/kg every 4 weeks

Duration 18 months

Rationale

Summary

Cosentyx (secukinumab) is a human interleukin-17A (IL-17A) antagonist that helps regulate inflammation associated with plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), enthesitis-related arthritis (ERA), and hidradenitis suppurativa (HS). Cosentyx binds to interleukin 17A (IL-17A) and prevents it from binding to its receptor inhibiting its ability to trigger an inflammatory response. Cosentyx should not be used in combination with other biological DMARDs or other tumor necrosis factor (TNF) blockers (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Cosentyx while maintaining optimal therapeutic outcomes.

References

1. Cosentyx [package insert]. New Hanover, NJ: Novartis Pharmaceutical Corp; November 2023.

Policy History

Date	Action
February 2015	New addition to PA
March 2015	Annual editorial review and reference update
June 2015	Annual review
September 2015	Annual review

January 2016	Addition of new indications active psoriatic arthritis (PsA) and active ankylosing spondylitis (AS) Policy number changed from 5.18.11 to 5.90.11
March 2016	Annual editorial review
September 2016	Annual editorial review Addition of not given concurrently with live vaccines per SME
December 2016	Annual review
June 2017	Annual review
September 2017	Annual editorial review and reference update Added age limit to renewal section and dosage limit requirements
December 2017	Annual review
June 2018	Addition of additional requirements to initiation criteria For diagnosis of AS: inadequate response, intolerance, or contraindication to at least 2 NSAIDs For diagnosis of PsA: inadequate response, intolerance or contraindication to a 3-month trial of at least ONE conventional DMARD For diagnosis of PsO: if the patient is intolerant or contraindicated to either therapy then the other treatment option needs to be tried Addition of conventional therapy and biological DMARDS to appendix
September 2018	Annual editorial review and reference update Addition of inflammatory bowel disease warning to regulatory status per SME
September 2019	Annual review
December 2019	Addition of requirement to trial preferred product
February 2020	Revised ankylosing spondylitis dosing to 300 mg every 4 weeks
March 2020	Annual review
July 2020	Addition of indication: non-radiographic axial spondyloarthritis (nr-axSpA)
September 2020	Annual review
December 2020	Annual editorial review. Added Appendix 2 with a list of preferred medications based on diagnosis and plan. Added PA quantity limits. Changed initial approval duration to 12 months
March 2021	Annual editorial review. Revised background and summary sections. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 1 updated
June 2021	Revised age limit for plaque psoriasis to 6 and older from 18 and older per newest package insert. Added dosing requirements and quantity limits for pediatric patients with plaque psoriasis. Also revised preferred products list for plaque psoriasis based on age
September 2021	Annual review
January 2022	Addition of indication: enthesitis-related arthritis. Reduced age requirement for PsA to 2 and older from 18 and older. Revised quantity limit chart and

	preferred products chart. Added Rinvoq as a preferred PsA product to chart (Appendix 2)
March 2022	Annual review. Added Skyrizi as a preferred PsA product to chart (Appendix 2)
May 2022	Added Rinvoq as a preferred AS product to chart (Appendix 2)
June 2022	Annual review
September 2022	Annual review
December 2022	Annual review
February 2023	Added Rinvoq as a preferred nr-axSpA product to chart (Appendix 2)
March 2023	Annual review
August 2023	Per PI update, added 300 mg injection to quantity limit chart
September 2023	Annual review
November 2023	Per PI update, added indication of hidradenitis suppurativa (HS). Revised FDA dosing language
January 2024	Also added 125 mg IV infusion.
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu

tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Ankylosing spondylitis (AS)	*must try **TWO** preferred products: Enbrel Humira** Rinvoq Taltz	*must try **ONE** preferred product: Enbrel Humira**
Non-radiographic axial spondyloarthritis (nr-axSpA)	*must try **TWO** preferred products: Cimzia Rinvoq Taltz	No preferred products
Plaque psoriasis (PsO) **Age 18+**	*must try **THREE** preferred products: Enbrel Humira** Otezla Skyrizi Stelara (SC) Taltz Tremfya	*must try **ONE** preferred product: Enbrel Humira**
Plaque Psoriasis (PsO) **Age 12-17**	*must try **THREE** preferred products: Enbrel Humira** Stelara (SC) Taltz	*must try **ONE** preferred product: Enbrel Humira**
Plaque Psoriasis (PsO) **Age 6-11**	*must try **THREE** preferred products: Enbrel Stelara (SC) Taltz	*must try **ONE** preferred product: Enbrel
Psoriatic arthritis (PsA) **Age 18+**	*must try **TWO** preferred products: Enbrel Humira** Otezla Rinvoq Stelara (SC) Skyrizi Taltz Tremfya Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**
Psoriatic arthritis (PsA) **Age 2-17**	No preferred products	No preferred products

**Including all preferred biosimilars (see reference product criteria)