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Last Review Date: December 12, 2025

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

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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

Bimzelx, 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

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Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

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. 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. **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. 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)

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- 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)
- 5. Active enthesitis-related arthritis (ERA)
 - a. 4 years of age or older
- 6. Hidradenitis Suppurativa (HS)
 - a. 18 years of age or older

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

- 1. Patient will not exceed the FDA labeled maintenance dose as outlined in the quantity limit chart below
- 2. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
- 3. 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
- 4. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
- 5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval Renewal Requirements

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

- 1. Plaque psoriasis (PsO)
 - a. 6 years of age or older
 - b. 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)

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2. Psoriatic arthritis (PsA)
 - a. 2 years of age or older
 - b. **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. 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. 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
6. Hidradenitis Suppurativa (HS)
 - a. 18 years of age or older

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

1. Condition has improved or stabilized with therapy
2. Patient will not exceed the FDA labeled maintenance dose as outlined in the quantity limit chart below
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

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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 <u>or</u> 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 <u>or</u> 300 mg at Weeks 0, 1, 2, 3, 4 then 150mg <u>or</u> 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 <u>or</u> 300 mg at Weeks 0, 1, 2, 3, 4 then 150mg <u>or</u> 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) | 75 mg SC syringe 150 mg SC syringe | 17 units per 365 days (Loading dose of 75 mg <u>or</u> 150 mg at Weeks 0, 1, 2, 3, 4 then 75 mg <u>or</u> 150 mg every 4 weeks) |
| Psoriatic arthritis (PsA) Age 2 - 17 only | | |
| Plaque psoriasis (PsO) Age 6 - 17 only | 150 mg SC syringe 125 mg/5 mL IV vial | 17 units per 365 days (Loading dose of 150 mg at Weeks 0, 1, 2, 3, 4 then 150 mg every 4 weeks) |
| Non-radiographic axial spondyloarthritis (nr-axSpA) | | |

Duration 12 months

Prior – Approval Renewal Limits

Quantity

| Diagnosis | Strength | Quantity |
|-----------|----------|----------|
|-----------|----------|----------|

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| Ankylosing spondylitis (AS) | 150 mg SC syringe 300 mg SC syringe 300 mg carton (2 of the 150 mg) SC syringe 125 mg/5 mL IV vial | 3 units per 84 days 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 300 mg carton (2 of the 150 mg) SC syringe 125 mg/5 mL IV vial | 3 units per 84 days 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 | 3 units per 84 days |
| Non-radiographic axial spondyloarthritis (nr-axSpA) | 150 mg SC syringe 125 mg/5 mL IV vial | 3 units per 84 days 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; October 2024.

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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 |

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| 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 |
| July 2024 | Reworded dosing agreement questions to refer to quantity limit chart |
| September 2024 | Annual review. Added Otezla as preferred option for PsO age 6-11 and age 12-17 |
| March 2025 | Annual review and reference update |
| December 2025 | Annual review. Added documentation requirement. Revised Appendix 2 |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

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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 |
| bimekizumab-bkzx | Bimzelx |
| brodalumab | Siliq |
| certolizumab | Cimzia |
| etanercept | Enbrel |
| golimumab | Simponi/Simponi Aria |
| guselkumab | Tremfya |
| infliximab | Remicade |
| infliximab-dyyb | Zymfentra |
| ixekizumab | Taltz |
| risankizumab-rzaa | Skyrizi |
| rituximab | Rituxan |
| 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 |

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| baricitinib | Olumiant |
| deucravacitinib | Sotyktu |
| tofacitinib | Xeljanz/XR |
| upadacitinib | Rinvoq |

Appendix 2 - List of Preferred Products

List of preferred products:

https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:

<https://www.fepblue.org/pharmacy/prescriptions#drug-lists>