Drug Coverage Policy

Effective Date……09/01/2025
Coverage Policy Number……PSM009
Policy Title……Inflammatory Conditions – Cosentyx Intravenous Preferred Specialty Management for Standard/Performance, Value/Advantage, Total Savings Plans

Inflammatory Conditions – Cosentyx Intravenous Preferred Specialty Management Policy for Employer Plans: Standard/Performance, Value/Advantage, Total Savings Prescription Drug Lists Plans

- Cosentyx® (secukinumab intravenous infusion – Novartis)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted

for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

Cosentyx intravenous, an interleukin (IL)-17A antagonist, is indicated in the following conditions:[1]

- **Psoriatic arthritis**, in adults with active disease.
- **Ankylosing spondylitis**, in adults with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.

Coverage Policy

POLICY STATEMENT

The Inflammatory Conditions program has been developed to encourage the use of the Preferred Products. For all medications, this program requires the patient to meet the respective standard *Prior Authorization Policy* criteria. Additionally, this program requires trial(s) of the Preferred Product(s) according to the table below, when clinically appropriate, prior to the approval of the Non-Preferred Products. There are also situations when trials of Non-Preferred Products will be considered; see criteria below. Other details of the program are as follows:

- **Approval Duration:** All approvals for continuation of therapy for Preferred and Non-Preferred Products are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other Products, noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

For more information on criteria within a Prior Authorization program by specific condition, refer to the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy.*

Preferred and Non-Preferred Products.¥

	Rheumatology		
	Ankylosing Spondylitis	**Non-Radiographic Axial Spondyloarthritis**	**Psoriatic Arthritis**
Step 1 Preferred	• Adalimumab Product^ (adalimumab – adbm/ Cyltezo, adalimumab-ryvk/Simlandi • Enbrel • Rinvoq • Taltz • Xeljanz/XR	• Cimzia • Rinvoq • Taltz	• Adalimumab Product^ (adalimumab – adbm/Cyltezo, adalimumab-ryvk/Simlandi • Enbrel • Otezla • Rinvoq • Rinvoq LQ • Skyrizi SC

			• Ustekinumab SC Products – Stelara SC, Selarsdi SC, ustekinumab-ttwe SC, Yesintek SC • Taltz • Tremfya • Xeljanz/XR
<u>Step 2</u> **Non-Preferred** (directed to **<u>TWO</u>** Step 1 agents) **[documentation required]**.	• Cosentyx Intravenous	• Cosentyx Intravenous	• Cosentyx Intravenous

[¥] For Non-Preferred Adalimumab Products, refer to the respective *Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy: Standard/Performance, Value/Advantage, and Total Savings Prescription Drug Lists (PSM013)*. For Non-Preferred Ustekinumab Products, refer to the Inflammatory Conditions – *Ustekinumab Subcutaneous Products Preferred Specialty Management Policy for Standard/Performance, Value/Advantage, and Total Savings Prescription Drug Lists (PSM021)*[^] A trial of more than one adalimumab product counts as ONE Preferred Product; A trial of more than one ustekinumab product counts as ONE Preferred Product; SC – Subcutaneous.

Cosentyx intravenous is considered medically necessary when the following non-preferred product exception criteria is met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Cosentyx Intravenous	**<u>Applies only when Cosentyx Intravenous is requested for coverage under the Prescription Drug Benefit</u>** **1. <u>Ankylosing Spondylitis – Initial Therapy</u>.** **A)** Approve for 6 months if the patient meets the following (i <u>and</u> ii): **i.** Patient meets the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria; AND **ii.** Patient has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz, and Xeljanz/XR **[documentation required]**. <u>Note</u>: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as **ONE** product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Cimzia, an infliximab product (e.g. Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts. **[documentation required]**.

B) If the patient has met criterion 1Ai (the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria), but criterion 1Aii is not met: A request for a Step 1 Product may be reviewed (adalimumab-adbm, Cyltezo, adalimumab-ryvk, Simlandi, Enbrel, Rinvoq, Taltz, Xeljanz tablets, or Xeljanz XR) using the respective standard *Inflammatory Conditions – Prior Authorization Policy* criteria.

2. Non-Radiographic Spondyloarthritis (nr-axSpA) – Initial Therapy.

A) Approve for 6 months if the patient meets the following (i and ii):

i. Patient meets the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria; AND

ii. Patient has tried TWO of Cimzia, Taltz, and Rinvoq **[documentation required]**.
Note: A trial of Enbrel, an adalimumab product (e.g., Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry), an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts. **[documentation required]**. A trial of multiple adalimumab products counts as **ONE** product.

B) If the patient has met criterion 2Ai (the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria), but criterion 2Aii is not met: A request for a Step 1 Product may be reviewed (Cimzia, Taltz, or Rinvoq) using the respective standard *Inflammatory Conditions – Prior Authorization Policy* criteria.

3. Psoriatic Arthritis – Initial Therapy.

A) Approve for 6 months if the patient meets the following (i and ii):

i. Patient meets the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria; AND

ii. Patient has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi subcutaneous, an ustekinumab subcutaneous product, Taltz, Tremfya, and Xeljanz/XR **[documentation required]**;
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. Examples of ustekinumab products include Stelara/ustekinumab, Imuldosa, Otulfi, Pyzchiva, ustekinumab-ttwe, Selarsdi, ustekinumab-aekn, Starjemza, Steqeyma, Wezlana, and Yesintek.A trial of multiple adalimumab products counts as **ONE** product. A trial of multiple ustekinumab products counts as **ONE** product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi **[documentation required]**. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as **ONE** product.

B) If the patient has met criterion 3Ai (the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria), but criterion 3Aii is not met: A request for a Step 1 Product may be reviewed (Enbrel, adalimumab-adbm, Cyltezo, adalimumab-ryvk, Simlandi, Otezla, Rinvoq, Rinvoq LQ, Skyrizi subcutaneous [pen or syringe], Stelara subcutaneous, Selsardi subcutaneous, ustekinumab-ttwe subcutaneous, Yesintek, Taltz, Tremfya, Xeljanz, Xeljanz XR) using the respective standard *Inflammatory Conditions – Prior Authorization Policy* criteria.

4. Ankylosing Spondylitis; nr-axSpA; or Psoriatic Arthritis – Patient is Currently Receiving Cosentyx (SC or IV).

A) Approve for 1 year if the patient meets the following (i and ii):

i. Patient meets the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria; AND

ii. Patient meets ONE of the following (a, b, c, or d):

a) Patient has Ankylosing Spondylitis and has tried TWO of Enbrel, an adalimumab product, Rinvoq, Taltz, and Xeljanz/XR **[documentation required]**; OR
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as **ONE** product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts **[documentation required]**.

b) Patient has nr-axSpA and has tried TWO of Cimzia, Taltz, and Rinvoq **[documentation required]**; OR
Note: A trial of Enbrel, an adalimumab product (e.g., Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, Yusimry), an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts **[documentation required]**. A trial of multiple adalimumab products counts as **ONE** product.

c) Patient has Psoriatic Arthritis and has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi subcutaneous, an ustekinumab subcutaneous product, Taltz, Tremfya, or Xeljanz/XR **[documentation required]**; OR
Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. Examples of ustekinumab products include Stelara/ustekinumab, Imuldosa, Otulfi, Pyzchiva, ustekinumab-ttwe, Selarsdi, ustekinumab-aekn, Starjemza, Steqeyma, Wezlana, and Yesintek. A trial of

	multiple adalimumab products counts as **ONE** product. A trial of multiple ustekinumab products counts as **ONE** product. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product. A trial of either or both Rinvoq products (Rinvoq and Rinvoq LQ) collectively counts as **ONE** product. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts **[documentation required]**. **d)** According to the prescriber, the patient with AS, nr-axSpA, or PsA has been established on Cosentyx intravenous or subcutaneous for at least 90 days; OR **B)** If the patient has met criterion 4Ai (the standard *Inflammatory Conditions – Cosentyx Intravenous Prior Authorization Policy* criteria), but criterion 4Aii is not met: A request for one of the following Products may be reviewed, using the respective standard *Inflammatory Conditions – Prior Authorization Policy* criteria: **i. Ankylosing Spondylitis:** Enbrel, adalimumab-adbm, Cyltezo, adalimumab-ryvk, Simlandi, Rinvoq, Taltz, Xeljanz tablets, or Xeljanz XR. **ii. nr-axSpA:** Cimzia, Taltz, or Rinvoq. **iii. Psoriatic Arthritis:** Enbrel, adalimumab-adbm, Cyltezo, adalimumab-ryvk, Simlandi, Otezla, Rinvoq, Rinvoq LQ, Skyrizi subcutaneous (pen or syringe), Stelara subcutaneous, Selsardi subcutaneous, ustekinumab-ttwe subcutaneous, Yesintek subcutaneous, Taltz, Tremfya, Xeljanz, Xeljanz XR.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

References

1. Cosentyx® [prescribing information]. East Hanover, NJ: Novartis; October 2023.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024
Selected Revision	Policy name was changed to as listed. **Ankylosing Spondylitis and Psoriatic Arthritis:** Humira (NDCs starting with 00074) and Hyrimoz (NDC's starting with 61314) were removed from the Preferred Products.	01/01/2025
Selected Revision	**For Psoriatic Arthritis:** Selsardi subcutaneous, ustekinumab-ttwe subcutaneous, and Yesintek	04/15/2025

	subcutaneous were added as Preferred ustekinumab subcutaneous products. A note was added indicating that a trial of multiple ustekinumab products counts as one product and examples of ustekinumab products were added including Stelara, Wezlana, Otufli, Pyzchiva, ustekinumab-ttwe, Selarsdi, Steqeyma, and Yesintek.	
Selected Revision	**Ankylosing Spondylitis and Psoriatic Arthritis:** adalimumab-adaz was removed as a Preferred Product. Throughout the policy, the note was updated for the examples of ustekinumab products which include Stelara, ustekinumab (unbranded Stelara), Imuldosa, Otulfi, Pyzchiva, ustekinumab-ttwe, Selarsdi, ustekinumab-aekn, Starjemza, Steqeyma, Wezlana, and Yesintek.	09/01/2025

The policy effective date is in force until updated or retired.