Drug Coverage Policy

Effective Date……11/01/2024
Coverage Policy Number……PSM006
Policy Title……Orencia Intravenous Preferred Specialty Management Policy for Employer Plans

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

- Orencia® (abatacept intravenous infusion - Bristol-Myers Squibb)

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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

Overview

Several products are available for use in inflammatory conditions such as rheumatoid arthritis and juvenile idiopathic arthritis.[1-4] This policy involves the use of the products listed above.

Medical Necessity Criteria

Policy Statement

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:

- **Continuation of Therapy:** Approval for a patient continuing therapy with a **Non-Preferred** subcutaneous or oral Product must be supported with verification, noted in the criteria as either **[verification in prescription claims history required]** or, if not available, as **[verification by prescriber required]**.
  - If the patient has at least 130 days of prescription claims history on file, claims history must support that the patient has received the Non-Preferred Product for the specified period of time (90 or 120 days) within a 130-day look-back period; OR
  - When 130 days of the patient's prescription claim history file is unavailable for verification, the prescriber must verify that the patient has been receiving the Non-Preferred Product for a specified period of time (90 or 120 days), AND that the patient has been receiving the Non-Preferred Product via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to the Non-Preferred Product).
  - For a patient continuing therapy, other conditions may also apply. Refer to criteria below.
- **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.

Preferred and Non-Preferred Products.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Step 1 **Preferred**	• Enbrel • Adalimumab Products – Humira (NDCs starting with 00074), Cyltezo/ adalimumab-adbm, Hyrimoz (NDCs starting	• Enbrel • Adalimumab Products – Humira (NDCs starting with 00074), Cyltezo/ adalimumab-adbm, Hyrimoz (NDCs starting	• Enbrel • Adalimumab Products – Humira (NDCs starting with 00074), Cyltezo/ adalimumab-adbm, Hyrimoz (NDCs starting with 61314)/

	with 61314)/ adalimumab-adaz, Simlandi/ adalimumab-ryvk • Tocilizumab SC Products – Actemra SC, Tyenne SC • Rinvoq • Xeljanz tablets/ Xeljanz XR tablets	with 61314)/ adalimumab-adaz, Simlandi/ adalimumab-ryvk • Tocilizumab SC Products - Actemra SC, Tyenne SC • Rinvoq/Rinvoq LQ • Xeljanz tablets/ Xeljanz oral solution	adalimumab-adaz, Simlandi/ adalimumab-ryvk • Otezla • Skyrizi SC • Stelara SC • Taltz • Tremfya • Rinvoq/ Rinvoq LQ • Xeljanz tablets/Xeljanz XR tablets
Step 2 **Non-Preferred** (directed to **TWO** Step 1 agents)	• Orencia Intravenous	• Orencia Intravenous	• Orencia Intravenous

Orencia 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 Products	Exception Criteria
Orencia Intravenous	**1. Rheumatoid Arthritis (RA) - Initial Therapy.** **A)** Approve for 6 months if patient meets BOTH of the following (i and ii) **i.** Patient meets the standard *Inflammatory Conditions – Orencia Intravenous Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has tried two of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, or Xeljanz/XR **[documentation required]**; OR Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. 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 tocilizumab intravenous (Actemra intravenous, biosimilar), Cimzia, an infliximab product (e.g.,

	Remicade, biosimilars), Kevzara, or Simponi (Aria or subcutaneous) also counts **[documentation required]**. **b)** According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder. **B)** If the patient has met criterion 1Ai (the standard *Inflammatory Conditions – Orencia Intravenous Prior Authorization Policy* criteria), but criterion 1Aii is not met: a request for a Step 1 Product may be reviewed (Actemra subcutaneous, Tyenne subcutaneous, Enbrel, Humira [NDCs starting with 00074], adalimumab-adbm, Cyltezo, Hyrimoz [NDCs starting with 61314], adalimumab-adaz, adalimumab-ryvk, Simlandi, Rinvoq, Xeljanz tablets, or Xeljanz XR) using the respective standard *Inflammatory Conditions Prior Authorization Policy* criteria. **2. Juvenile Idiopathic Arthritis – Initial Therapy.** **A)** Approve for 6 months if patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Inflammatory Conditions – Orencia Intravenous Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq/Rinvoq LQ, and Xeljanz **[documentation required]**; OR Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as ONE product. 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 tablets and Xeljanz oral solution) 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 tocilizumab intravenous (Actemra intravenous, biosimilar), Kevzara, Orencia subcutaneous, an infliximab product (e.g., Remicade, biosimilar), or Simponi Aria also counts **[documentation required]**. **b)** According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder. **B)** If the patient has met criterion 2Ai (the standard *Inflammatory Conditions – Orencia Intravenous Prior Authorization Policy* criteria), but criterion 2Aii is not met, a request for a Step 1 Product may be reviewed (Actemra subcutaneous, Tyenne subcutaneous, Enbrel, Humira [NDCs starting with 00074], adalimumab-adbm, Cyltezo, Hyrimoz [NDCs starting with 61314], adalimumab-adaz, adalimumab-ryvk, Simlandi, Rinvoq, Rinvoq LQ, Xeljanz tablets, or Xeljanz oral solution) using the

respective standard *Inflammatory Conditions – Prior Authorization Policy* criteria.

3. <u>Psoriatic Arthritis, Initial Therapy</u>.

A) Approve for 6 months if patient meets BOTH of the following (i <u>and</u> ii):

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

ii. Patient meets ONE of the following (a <u>or</u> b):

a) Patient has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi subcutaneous, Stelara subcutaneous, Taltz, Tremfya, or Xeljanz/XR **[documentation required]**; OR
<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 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]**.

b) According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder.

B) If the patient has met criterion 3Ai (the standard *Inflammatory Conditions – Orencia Intravenous Prior Authorization Policy* criteria), but criterion 3Aii is not met, a request for a Step 1 Product may be reviewed (<u>Enbrel, Humira [NDCs starting with 00074], adalimumab-adbm, Cyltezo, Hyrimoz [NDCs starting with 61314], adalimumab-adaz, adalimumab-ryvk, Simlandi, Otezla, Rinvoq, Rinvoq LQ, Skyrizi subcutaneous (pen or syringe), Stelara subcutaneous, Taltz, Tremfya, Xeljanz tablets, or Xeljanz XR</u>) using the respective standard *Inflammatory Conditions – Prior Authorization Policy* criteria.

4. <u>Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, or Psoriatic Arthritis – Patient is Currently Receiving Orencia (Subcutaneous or Intravenous)</u>.

A) Approve for 1 year if the patient meets BOTH of the following (i <u>and</u> ii):

i. Patient meets the standard *Inflammatory Conditions – Orencia Intravenous Policy* criteria; AND

ii. Patient meets ONE of the following (a, b, c, d, e, <u>or</u> f):

a) Patient has <u>Rheumatoid Arthritis</u> and has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq, or Xeljanz/XR **[documentation required]**; OR
<u>Note</u>: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne

	subcutaneous. A trial of multiple tocilizumab products counts as **ONE** product. 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 tocilizumab intravenous (Actemra intravenous, biosimilar), Cimzia, an infliximab product (e.g., Remicade, biosimilars), Kevzara, or Simponi (Aria or subcutaneous) also counts **[documentation required]**. **b)** Patient has Juvenile Idiopathic Arthritis and has tried TWO of a tocilizumab subcutaneous product, Enbrel, an adalimumab product, Rinvoq/Rinvoq LQ, and Xeljanz tablets or oral solution **[documentation required]**; OR Note: Examples of tocilizumab subcutaneous products include Actemra subcutaneous and Tyenne subcutaneous. A trial of multiple tocilizumab products counts as **ONE** product. 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 tablets and Xeljanz oral solution) 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 tocilizumab intravenous (Actemra intravenous, biosimilar), Kevzara, Orencia intravenous, an infliximab product (e.g., Remicade, biosimilars), or Simponi Aria also counts **[documentation required]**. **c)** Patient has Psoriatic Arthritis AND has tried TWO of Enbrel, an adalimumab product, Otezla, Rinvoq/Rinvoq LQ, Skyrizi subcutaneous, Stelara subcutaneous, 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. 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 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 has been established on Orencia intravenous for at least 90 days; OR

	e) According to the prescriber, the patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder; OR **f)** Patient has been established on Orencia subcutaneous for at least 90 days and prescription claims history indicates at least a 90-day supply of Orencia subcutaneous was dispensed within the past 130 days **[verification in prescription claims history required]**, or if claims history is not available, according to the prescriber **[verification by prescriber required]**. Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Orencia subcutaneous for at least 90 days AND the patient has been receiving Orencia subcutaneous via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Orencia subcutaneous). **B)** If the patient has met criterion 4Ai (the standard *Inflammatory Conditions – Orencia 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. Rheumatoid Arthritis:** Actemra subcutaneous, Tyenne subcutaneous, Enbrel, Humira (NDCs starting with 00074), adalimumab-adbm, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-ryvk, Simlandi, Rinvoq, Xeljanz tablets, or Xeljanz XR. **ii. Juvenile Idiopathic Arthritis:** Actemra subcutaneous, Tyenne subcutaneous, Enbrel, Humira (NDCs starting with 00074), adalimumab-adbm, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-ryvk, Simlandi, Rinvoq, Rinvoq LQ, Xeljanz tablets, or Xeljanz oral solution. **iii. Psoriatic Arthritis:** Enbrel, Humira (NDCs starting with 00074), adalimumab-adbm, Cyltezo, Hyrimoz (NDCs starting with 61314), adalimumab-adaz, adalimumab-ryvk, Simlandi, Otezla, Rinvoq, Rinvoq LQ, Skyrizi subcutaneous (pen or syringe), Stelara subcutaneous, Taltz, Tremfya, Xeljanz tablets, or Xeljanz XR. **5. Other Conditions.** Approve Orencia intravenous (initial therapy for a duration as directed or 1 year for a patient continuing therapy) if the patient meets the standard *Inflammatory Conditions – Orencia Intravenous Prior Authorization Policy* criteria.

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. Orencia® injection [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2021.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024

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