Drug Coverage Policy

Effective Date.....12/01/2024
Coverage Policy Number.....PSM008
Policy Title.....Multiple Sclerosis and Ulcerative Colitis – Zeposia Preferred Specialty Management – Individual and Family Plans

Multiple Sclerosis and Ulcerative Colitis – Zeposia Preferred Specialty Management Policy for Individual and Family Plans

- Zeposia® (ozanimod capsules – Celgene/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
Zeposia, a sphingosine 1-phosphate receptor modulator, is indicated for the following uses:[1]

- **Relapsing forms of multiple sclerosis**, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in adults.
- **Ulcerative colitis**, in adults with moderately to severely active disease.

For more information on criteria within a Prior Authorization program by specific condition, refer to the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy.*

Individual and Family Plans Preferred and Non-Preferred Products.[¥]

	Multiple Sclerosis	Ulcerative Colitis
Step 1 **Preferred**	• **dimethyl fumarate** (generic for Tecfidera)	• **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [by Sandoz/Novartis], **Adalimumab – adbm/Cyltezo**, **adalimumab-ryvk/Simlandi**, or **Humira** [by AbbVie]) • **Skyrizi SC (on-body injector)** • **Stelara SC**
Step 2 **Non-Preferred** (directed to **ONE** Step 1 Products)	• Zeposia	• --
Step 3 **Non-Preferred** (directed to **TWO** Step 1 Products)	--	• Zeposia

[¥] For Non-Preferred Adalimumab Products, refer to the *Inflammatory Conditions – Adalimumab Products Preferred Specialty Management Policy*; ^ A trial of more than one adalimumab product counts as ONE Preferred Product; SC – Subcutaneous.

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 above, 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.

Medical Necessity Criteria

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Zeposia	**1. Multiple Sclerosis.** **A)** Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has been established on Zeposia for ≥ 120 days; OR **b)** Patient has tried dimethyl fumarate (generic for Tecfidera) Note: A trial of Bafiertam, Gilenya, Mayzent, Ponvory, Tascenso ODT, Tecfidera, or Vumerity also counts. **2. Ulcerative Colitis – Initial Therapy.** **A)** Approve for 6 months if the patient meets BOTH of the following (i and ii): **i.** Patient meets the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria; AND **ii.** Patient has tried TWO of an adalimumab product, Skyrizi subcutaneous, and Stelara subcutaneous. Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars, Zymfentra), Simponi subcutaneous, Entyvio intravenous or subcutaneous, Omvoh intravenous or subcutaneous, Skyrizi intravenous, or Stelara intravenous also counts. **B)** If the patient has met criterion 2Ai (the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria), but criterion 2Aii is not met, a request for a Preferred Product may be reviewed (adalimumab-adaz, adalimumab-adbm, Cyltezo, Humira [by AbbVie], Hyrimoz [NDCs starting with 61314], adalimumab-ryvk, Simlandi, Skyrizi subcutaneous (on-body injector), Stelara subcutaneous) using the respective standard *Inflammatory Conditions Prior Authorization Policy* criteria. **3. Ulcerative Colitis – Patient is Currently Receiving Zeposia.** **A)** Approve for 1 year if the patient meets BOTH of the following (i and ii):

	i. Patient meets the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria; AND **ii.** Patient meets ONE of the following conditions (a or b): **a)** Patient has tried TWO of an adalimumab product, Skyrizi subcutaneous, and Stelara subcutaneous; OR Note: Examples of adalimumab products include Humira, Abrilada, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of an infliximab product (e.g., Remicade, biosimilars, Zymfentra), Simponi subcutaneous, Entyvio intravenous or subcutaneous, Omvoh intravenous or subcutaneous, Skyrizi intravenous, or Stelara intravenous also counts. **b)** Patient has been established on Zeposia for at least 90 days and prescription claims history indicates at least a 90-day supply of Zeposia was dispensed within the past 130 days **[verification in prescription claims history required]** if claims history is not available, according to the prescriber **[verification by prescriber required]**. Note: In cases where 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 Zeposia for at least 90 days AND the patient has been receiving Zeposia via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Zeposia). **B)** If the patient has met criterion 3Ai (the standard *Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy* criteria), but criterion 3Aii is not met, a request for a Preferred Product may be reviewed (adalimumab-adaz, adalimumab-adbm, Cyltezo, Humira [by AbbVie], Hyrimoz [NDCs starting with 61314], adalimumab-ryvk, Simlandi, Skyrizi subcutaneous (on-body injector), Stelara subcutaneous) using the respective standard *Inflammatory Conditions 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. Zeposia® capsules [prescribing information]. Princeton, NJ: Celgene/Bristol Myers Squibb; August 2023.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	12/01/2024

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