Zeposia® (ozanimod)
Effective 03/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Zeposia® (ozanimod) is indicated for the treatment of:
- Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome (CIS), relapse-remitting disease (RRMS), and active secondary-progressive disease (SPMS)
- Moderate to severe ulcerative colitis (UC)

Coverage Guidelines
Authorizations requests will be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Clinically Isolated Syndrome (CIS), Relapse-remitting Multiple Sclerosis (RRMS), Active Secondary-Progressive MS (SPMS)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of clinically isolated syndrome (CIS) **OR** relapse-remitting multiple sclerosis (RRMS) **OR** active secondary-progressive multiple sclerosis (SPMS)*
2. The prescriber is a neurologist or medication is being prescribed in consultation with a neurologist
3. Provider documents medical necessity for use of Zeposia instead of Gilenya
4. Paid claim or physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following disease modifying multiple sclerosis agents:

a. Aubagio® (teriflunomide)
b. glatiramer acetate therapy
c. interferon therapy
d. Ocrevus® (ocrelizumab)
e. dimethyl fumarate or Vumerity®

5. Quantity requested is ≤ 1 unit/day

*For requests that document SPMS, active disease must be confirmed.

Ulcerative Colitis†

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe ulcerative colitis
2. Prescriber is a gastroenterologist or consult notes from a gastroenterology office are provided
3. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** anti-TNF agents that is FDA-approved for ulcerative colitis
4. Appropriate dosing
5. Member is not currently receiving concomitant therapy with immunomodulators or biologic agents
6. Requested quantity is ≤ 1 unit/day

†New members currently stable on Zepsoia® can be approved for ulcerative colitis without documentation of failed trials with the conventional therapies.

Continuation of Therapy

- For **RRMS**: Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.
- For **SPMS**: Reauthorization requires physician attestation of active disease, continuation of therapy and positive response to therapy.
- For **CIS**: Reauthorization will be evaluated on a case by case basis
- For **Ulcerative Colitis**: Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations

1. Initial authorizations will be granted for:
   a. Ulcerative colitis: 6 months
   b. All other indications: 12 months
2. Reauthorizations will be granted for 12 months.
3. The following quantity limits apply:

Zeposia® (ozanimod) 7-day starter pack	1 pack
Zeposia® (ozanimod) Starter kit	1 pack
Zeposia® (ozanimod) 0.92mg	30 capsules per 30 days

References

1. Zeposia (ozanimod) [prescribing information]. Summit, NJ: Celgene Corporation; May 2021.

Review History

11/17/2021 – Created and Reviewed Nov P&T; Zeposia removed from Multiple sclerosis criteria and added to own criteria for multiple sclerosis and ulcerative colitis. Matched MH UPPL for 1/1/2022 implementation. Effective 01/01/2022

01/11/2023 – Reviewed and updated for Jan P&T. Matched MH UPPL. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members. Trial with Entyvio was removed from UC criteria. Clarified initial approval durations: 6 months for UC, 12 months for other indications. Effective 3/1/23.

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