AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Zeposia			Page:	1 of 3
Effective Date:	5/1/2024			Last Review Date:	9/2023; 4/2024
Applies to:	☐Illinois ☒New Jersey ☐Pennsylvania Kids	☐Florida ☐Maryland ☐Virginia		☐Florida Kids ☐Michigan ☐Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Zeposia under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Zeposia is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
B. Zeposia is indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Zeposia

Policy/Guideline:

Documentation:
Submission of the following information is necessary to initiate the prior authorization review:

Ulcerative colitis (UC):

A. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties:
The medication must be prescribed by or in consultation with one of the following:

A. Ulcerative colitis: gastroenterologist
B. Multiple sclerosis: neurologist

Criteria for Initial Approval:

A. Relapsing Forms of Multiple Sclerosis

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse). Requests also require that the patient is unable to take the required number of formulary alternatives (2) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

B. Clinically Isolated Syndrome

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis. Requests also require that the patient is unable to take the required number of formulary alternatives (2) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

C. Ulcerative Colitis

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active ulcerative colitis. Requests also require that the patient is unable to take TWO formulary alternatives (a preferred adalimumab product, Rinvoq) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

Continuation of Therapy:

A. Relapsing Forms of Multiple Sclerosis and Clinically Isolated Syndrome

Authorization of 12 months may be granted when the member is experiencing disease stability or improvement while receiving Zeposia.

B. Ulcerative Colitis

1. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis who achieve or maintain a positive clinical response as evidenced

by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

i. Stool frequency
ii. Rectal bleeding
iii. Urgency of defecation
iv. C-reactive protein (CRP)
v. Fecal calprotectin (FC)
vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Other:

A. For all indications: Zeposia will not be used concomitantly with immunomodulators, biologic drugs, targeted synthetic drugs, or disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
B. For multiple sclerosis: authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limits:

- Zeposia (ozanimod) 7-Day Starter Pack: 1 Starter Pack (7 capsules) per 7 days
- Zeposia (ozanimod) Starter Kit: 1 Starter Kit (37 capsules) per 37 days
- Zeposia (ozanimod) (28-day) Starter Kit (one 7-Day Starter Pack and twenty-one 0.92 mg capsules): 1 Starter Kit (28 capsules) per 28 days
- Zeposia (ozanimod) 0.92 mg capsules: 30 capsules per 30 days

References:

1. Zeposia [package insert]. Summit, NJ: Celgene Corporation; April 2022.
2. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
3. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020; 158:1450-1461.