| Effective date: 09/01/2021 |
| --- |
| Review date: 06/2021, 05/2022, 12/2022<br>Scope: Medicaid |

# SPECIALTY GUIDELINE MANAGEMENT

## ZEPOSIA (ozanimod)

## POLICY

### I. INDICATIONS

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 Indication
Zeposia is indicated for the treatment of:

a. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
b. Moderately to severely ulcerative colitis (UC) in adults.

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

### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
**Ulcerative colitis (UC):**

A. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
B. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

### III. 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, clinically isolated syndrome and secondary progressive disease for those who continue to experience relapse). Members will not use Zeposia concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

**B. Moderately to Severely Active Ulcerative Colitis (UC)**

Authorization of 12 months may be granted for members for the treatment of moderately to severely active ulcerative colitis when one of the following are met:

1. The member meets one of the following:
   a. Member has previously received a biologic or targeted synthetic disease modifying drug (e.g., Xeljanz) indicated for treatment of moderately to severely active ulcerative colitis.

b. Member has had an inadequate response, intolerance or contraindication to at least a 3 month trial of one conventional therapy option (see Appendix A).
c. Member has had an inadequate response, intolerance or contraindication to at least a 3 month trial to one of the following: Humira or Rinvoq
d. Members who have been hospitalized for acute severe UC (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia).

2. Zeposia will not be used concomitantly with immunomodulators, biologic therapy, or targeted synthetic drugs.

## IV. CONTINUATION OF THERAPY

### A. Relapsing Forms of Multiple Sclerosis and Clinically Isolated Syndrome

Authorization of 12 months may be granted when both of the following are met:

1. The member is experiencing disease stability or improvement while receiving Zeposia.
2. Zeposia will not be used concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

### B. Moderately to Severely Active Ulcerative Colitis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis when both of the following are met:

1. The member meets one of the following:
   a. The member has achieved or maintained remission.
   b. The member has achieved or maintained 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. Endoscopic appearance of the mucosa
      vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)
2. Zeposia will not be used concomitantly with immunomodulators, biologic therapy, or targeted synthetic drugs.

## V. QUANTITY LIMIT

Zeposia starter Pack or Zeposia 0.92mg: one tablet per day

## VI. APPPENDIX A

### Examples of Conventional Therapy Options for UC

**1.** Mild to moderate disease – induction of remission:
   **a.** Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
   **b.** Rectal mesalamine (e.g., Canasa, Rowasa)

   **c.** Rectal hydrocortisone (e.g., Colocort, Cortifoam)
   **d.** Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
   **a.** Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
   **b.** Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   **a.** Prednisone, hydrocortisone IV, methylprednisolone IV
   **b.** Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
   **a.** Azathioprine, mercaptopurine
   **b.** Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
   **a.** Alternative: rectal mesalamine

## VII. REFERENCES

1. Zeposia [package insert]. Summit, NJ: Celgene Corporation; June 2021.