Effective date: 09/01/2021
Review date: 06/2021 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. 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).

B. Moderately to Severely Active Ulcerative Colitis (UC)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic disease modifying drug (e.g., Xeljanz) indicated for treatment of moderately to severely active ulcerative colitis.
2. Authorization of 12 months may be granted for treatment of moderately to severely active UC when the member has had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix A).
3. Authorization of 12 months may be granted for members who have been hospitalized for acute severe UC (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia).

III. CONTINUATION OF THERAPY

For all indications: Authorization of 12 months may be granted to members who are using Zeposia for an indication outlined in section II and who achieve or maintain a positive clinical response with Zeposia as evidenced by disease stability or improvement in signs and symptoms of the condition.

IV. OTHER

Members will not use Zeposia concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

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.