Clinical Policy Title:	ozanimod
Policy Number:	RxA.649
Drug(s) Applied:	Zeposia®
Original Policy Date:	09/14/2020
Last Review Date:	08/27/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of relapsing multiple sclerosis (RMS), including clinically isolated syndrome, or relapsing remitting disease, or active secondary progressive disease.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Ulcerative colitis (must meet all):

1. Diagnosis of ulcerative colitis;
2. Patient meets one of the following (a or b):
   a. Trial and failure of ≥ 3 months of at least one (1) conventional agent (azathioprine, 6-mercaptopurine, aminosalicylate) unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroids (e.g., prednisone, methylprednisolone, budesonide) unless contraindicated or significant adverse effects are experienced;
3. Trial and failure of at least two (2) of the following agents: adalimumab (adalimumab-adaz, Amjevita, Hadlima, Humira, Yusimry), Simponi, Stelara, Rinvoq, Xeljanz/XR, unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All the indication in Section (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Zeposia. Package insert. Celgene. 2020. Accessed August 27, 2024.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158(5):1450-1461. Accessed August 27, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/11/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.4 was updated to remove trial and failure criteria, “Trial and failure of at least 2 preferred disease modifying therapies, at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;”. 2. Initial Approval Criteria 1.B was updated to include a new indication, "Ulcerative colitis”. 3. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	07/9/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria I.B.4.a was updated to add failure of a trial of azathioprine, 6-mercaptopurine, or aminosalicylate (e.g.,sulfasalazine) or corticosteroid (e.g., prednisone, methylprednisolone, etc), at upto maximally indicated doses, unless contraindicated or clinically significant adverse events are experienced . 2. Initial Approval Criteria 1.B.4.b was updated in include, patient has been previously treated with at least one other biologic DMARD that is FDA approved for the treatment of ulcerative colitis. 3. Initial Approval Criteria I.B.5 was updated to include failure of two(2) of the following: Inflectra®, Renflexis™, , Stelara®, Humira® or Xeljanz®/Xeljanz XR®, each used for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced.	12/16/21	01/17/22
Policy was reviewed: 1. Initial Approval Criteria, I.B.5: Updated trial and failure criteria from Failure of two (2) of the following for ≥ 3 months: Humira®, Cimzia®, Inflectra®, Renflexis™,	04/01/22	04/18/22

Stelara®, unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of at least one (2) of the following agents: Cimzia®, Humira® or Stelara® unless contraindicated or clinically significant adverse effects are experienced.		
Policy was reviewed: 1. Initial Approval Criteria, I.B.5: Updated trial and failure criteria to include drug Rinvoq® and Xeljanz/XR®. 2. References were reviewed and updated.	10/03/2022	10/19/2022
Policy was reviewed: 1. Initial Approval Criteria, I.B.5: Updated trial and failure criteria to include new preferred brand, Amjevita™. 2. References were reviewed and updated	04/06/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Updated trial and failure criteria to include Humira biosimilar. 2. Updated Approval duration. 3. Removed responding positively criteria. 4. References were reviewed and updated.	11/10/2023	10/19/2023
Policy was reviewed: 1. Removed age and dose restrictions 2. Added Mayo Score ≥ 6 for UC dx for consistency	3/1/2024	2/28/2024
Policy was reviewed: 1. Removed Mayo score for UC. 2. Removed prescriber requirements. 3. References were reviewed and updated.	8/27/2024	8/27/2024