Clinical Policy Title:	vedolizumab
Policy Number:	RxA.735
Drug(s) Applied:	Entyvio®
Original Policy Date:	04/18/2022
Last Review Date:	8/26/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Crohn's Disease (must meet all**):**

1. Diagnosis of Crohn's Disease (CD);
2. Trial and failure of at least two (2) of the following agents: adalimumab (Humira®, Amjevita™, Hadlima™, Yusimry™, or adalimumab-adaz), Cimzia®, Skyrizi®, Stelara®, or Rinvoq, unless contraindicated or clinically significant adverse effects are experienced;
3. Member meets one of the following (a or b):
   a. Trial and failure of a ≥ 3 months of at least one (1) conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]), unless contraindicated or clinically significant adverse effects are experienced;
   b. Trial and failure of corticosteroid treatment (e.g., prednisone, methylprednisolone, budesonide), unless contraindicated or significant adverse effects experienced.

Approval Duration
All Lines of Business (except Medicare): 12 months

B. Ulcerative Colitis (must meet all)**:**

1. Diagnosis of Ulcerative Colitis (UC);
2. Member 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 treatment (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 (Humira®, Amjevita™, Hadlima™, Yusimry™, or adalimumab-adaz), 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 Indications in Section I (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. Colombel JF, Sandborn WJ, Rutgeerts P, et.al. Adalimumab for Maintenance of Clinical Response and Remission in Patients With Crohn`s Disease: The CHARM Trial. Gastroenterology 2007; 132:52-65. Available at: https://pubmed.ncbi.nlm.nih.gov/17241859/. Accessed December 13, 2023.
2. Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014; 147: 702-705. Available at: https://www.gastrojournal.org/article/S0016-5085(14)00918-4/fulltext?referrer=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F. Accessed December 13, 2023.
3. Bernell O, Lapidus A, Hellers G. Risk Factors for Surgery and Postoperative Recurrence in Crohn's Disease. Annals of Surgery. 2000; 231(1): 38-45. Available at: https://pubmed.ncbi.nlm.nih.gov/10636100/. Accessed December 13, 2023.
4. Lichtenstein GR, Loftus Jr. EV, Isaacs KI, Regueiro MD, Gerson LB, and Sands BE. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018; 113:481-517. Available at: https://journals.lww.com/ajg/Fulltext/2018/04000/ACG_Clinical_Guideline__Management_of_Crohn_s.10.aspx. Accessed August 23rd, 2024.
5. 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. Available at: https://www.gastrojournal.org/article/S0016-5085(20)30018-4/fulltext?referrer=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F. Accessed August 23rd, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
RxA.592.Bilogic_DMARDs was last reviewed and updated on 01/05/2022 and archived on 04/18/2022. For details, please refer to RxA.592.Bilogics_DMARDs.	01/05/2022	04/18/2022
Drug specific policy for Entyvio was created based on RxA.592.Bilogics_DMARDs: 1. Initial Approval Criteria, I.A.4: Updated to remove Medical justification supports inability to use immunomodulators (see Appendix D). 2. Initial Approval Criteria, I.A.5: Updated trial and failure criteria from Failure of two (2) of the following for ≥ 3 months: Humira®, Cimzia®, Inflectra®, Renflexis™, 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. 3. Initial Approval Criteria, I.B.5: Updated trial and failure criteria from Failure of two (2) of the following: Inflectra®, Renflexis™, Simponi®,	02/14/2022	04/18/2022

Stelara®, Humira® or Xeljanz®/Xeljanz XR®, each used for ≥ 3 months unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of at least two (2) of the following agents: Humira®, Simponi® or Stelara® unless contraindicated or clinically significant adverse effects are experienced; 4. Initial Approval Criteria, I.A.6 and I.B.6: Updated dosing criteria from Dose does not exceed maximum dose indicated in background to Dose does not exceed 300 mg per dose. 5. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.6 and I.B.7: Updated dosing criteria from Dose does not exceed 300 mg per dose to Dose does not exceed 300 mg at weeks 0, 2, and 6, followed by maintenance dose of 300 mg every 8 weeks. 2. Initial Approval Criteria, I.B.4: Updated to inlclude new documentation criteria, Documentation of a Mayo Score ≥ 6. 3. Initial Approval Criteria I.A.5: Updated to add Amjevita™ and Syrizi ® as trial and failure options. 4. Initial Approval Criteria I.B.6: Updated to add Amjevita™, Rinvoq®, Xeljanz®/XR as trial and failure options. 5. References were reviewed and updated.	03/27/2023	04/13/2023
Policy was reviewed: 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Updated trial and failure criteria to include Humira biosimilar. 4. Updated approval duration. 5. Removed reauthorization requirement for positive response to therapy. 6. References were reviewed and updated.	12/13/2023	01/01/2024
Policy was reviewed: 1. Removed: “Exception: If one biologic DMARD that is FDA-approved for ulcerative colitis has been previously tried, then trial of a conventional systemic agent is not required”	3/1/2024	3/1/2024
Policy was reviewed: 1. Added Rinvoq to trial and failure for CD	8/26/2024	09/12/2024

2. Removed prescriber specialty. 3. Removed Mayo score from UC.		