MVP Health Care Medical Policy

Medicare Part B: ENTYVIO (vedolizumab)

Type of Policy:	**Drug/Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**1/01/2024**
Effective Date:	**01/01/2024**

Related Policies:

Inflammatory Biologic Drug Therapy

Experimental or Investigational Procedures

Infliximab

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Drugs Requiring Prior Authorization (covered under the medical benefit)

J3380 Entyvio (vedolizumab, injection 1mg)

Overview/Summary of EvidenceENTYVIO is an integrin receptor antagonist indicated for adult ulcerative colitis and adult Crohn's disease. Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Providers should consider withholding treatment in patients who develop a severe infection while on treatment with ENTYVIO. Providers should perform screening for tuberculosis (TB) according to the local practice.

Indications/Criteria

Coverage is provided in the following conditions:

Universal Criteria:

- Patient is at least 18 years of age; AND

- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND

- Patient is not on concurrent treatment with another TNF-inhibitor, biologic response modifier, natalizumab products or other non-biologic agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.);

- Coverage duration (unless otherwise specified for applicable indication)
    - Initial coverage up to 3 months
    - Continuation of coverage 12 months

For the treatment of **Crohn's disease**:

Documented moderate to severe active disease; AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, certolizumab, or infliximab

Continuation of therapy will require documentation of:

Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extra intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score].

For the treatment of **Ulcerative Colitis**:

Documented moderate to severe active disease; AND
• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate); OR

• Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab, golimumab, or infliximab
- Requests for patients with moderately severe UC, who are naïve to biologic therapies will be reviewed on a case-by-case basis consistent with the AGA guidelines.

Continuation of therapy will require documentation of:

Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity, tapering or discontinuation of corticosteroid therapy, and/or an improvement on a disease activity scoring tool [e.g., an improvement on the Ulcerative Colitis Endoscopic Index of Severity (UCEIS) score or the Mayo Score].

Management of **Immune Checkpoint Inhibitor-Related Diarrhea/Colitis**:

• Patient has been receiving therapy with an immune checkpoint inhibitor (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, etc.); AND

• Patient has moderate (grade 2) to severe (grade 3-4) diarrhea or colitis related to their immunotherapy

Continuation of therapy will require documentation of:

May not be renewed

Exclusions

Age, dose, frequency outside of FDA approved labeling

References

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3. 3. Kornbluth A, Sachar DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010 Mar;105(3):501-23.
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12. 12. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019 Mar;114(3):384-413.

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14. ACG Clinical Guidline: Ulcerative Colitis in Adults. The American Journal of Gastroenterology: March 2019 - Volume 114 - Issue 3 - p 384-413 doi: 10.14309/ajg.0000000000000152. Accessed: ACG Clinical Guideline: Ulcerative Colitis in Adults : Official journal of the American College of Gastroenterology | ACG (lww.com)