



## MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent licensee of the Blue Cross and Blue Shield Association

# Pharmacy Medical Policy Entyvio (Vedolizumab) Policy

### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Coding Information](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)
- [Endnotes](#)
- [Forms](#)

### Policy Number: 162

BCBSA Reference Number: None

### Related Policies

- Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy #621

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

**Note:** All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

| Standard Formulary          |                  |
|-----------------------------|------------------|
| Drug                        | Formulary Status |
| Entyvio® IV ( Vedolizumab ) | PA required      |

**We may cover** Entyvio® IV ( vedolizumab ) when **all** of the following criteria are met:

- A documented diagnosis of moderately to severely active Crohn's Disease

**AND**

- Age is equal to or greater than 18 years

**AND**

- Treatment failure with or contraindication to one (1) of the following drugs within the previous 130 days:
  - Corticosteroids (e.g. prednisone, prednisolone, methylprednisolone, budesonide)
  - Immunosuppressants / Immunomodulators (e.g. 6-mercaptopurine, azathioprine, methotrexate);

**AND**

- The drug is prescribed by a board-certified or board eligible gastroenterologist.

**We may cover** Entyvio® IV ( vedolizumab ) when **all** of the following criteria are met:

- A documented diagnosis of moderately to severely active Ulcerative Colitis

**AND**

- Age is equal to or greater than 18 years

**AND**

- Treatment failure with or contraindication to one (1) or more classes of the following classes within the previous 130 days:
  - Corticosteroids (e.g. prednisone, prednisolone, methylprednisolone, budesonide)
  - 5-Aminosalicylates (e.g. sulfasalazine, mesalamine, olsalazine, balsalazide)
  - Immunosuppressants / Immunomodulators (e.g. 6-mercaptopurine, azathioprine, methotrexate);

**AND**

- The drug is prescribed by a board-certified or board eligible gastroenterologist.

**RENEWAL CRITERIA**

- **We may cover** Entyvio® IV ( Vedolizumab ) for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet initial approval criteria
  - Individual is receiving ongoing monitoring for TB and other active infections
  - Absence of unacceptable toxicity from the medication such as anaphylaxis or other serious allergic reactions, severe infections, Progressive Multifocal Leukoencephalopathy (PML), jaundice or other evidence of significant liver injury
  - Diagnosis of **ANY ONE** of the following:
    - Crohn's Disease if response to treatment is 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 extraintestinal 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).
    - Ulcerative Colitis if response to treatment is 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, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), 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).

**For non-formulary/non-covered medications, requests must meet criteria above and the member must have had a previous treatment failure with or a contraindication to two covered formulary alternatives when available.**

We do not cover the medications listed above for other conditions not listed above.

## **CPT Codes / HCPCS Codes / ICD-9 Codes**

*The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

### **CPT Codes**

There is no specific CPT code for this service.

### **Individual Consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts  
Pharmacy Operations Department  
25 Technology Place  
Hingham, MA 02043  
Tel: 1-800-366-7778  
Fax: 1-800-583-6289

### **Managed Care Authorization Information**

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization.  
Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.

### **PPO and Indemnity Authorization Information**

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization.  
Pharmacy Operations: (800)366-7778

- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.

## Policy History

| Date     | Action  |
|----------|---|
| 8/2022   | Updated Criteria for both Crohn's and UC.                                 |
| 4/1/2021 | Implement new standalone policy for Entyvio <sup>®</sup> J3380 or j3380 . |

## References

1. Entyvio<sup>®</sup> [Product Information]. Lexington, MA. Takeda Pharmaceuticals U.S.A., Inc.; Nov 2020.

**To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:**

<https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>