Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Vedolizumab (Entyvio®)	MP-RX-FP28-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	7/22/2026
			Last Review Date: 7/22/2026	Frequently Revision: Annual

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of Vedolizumab (Entyvio®), an integrin receptor antagonist approved by the Food and Drug Administration (FDA) for the treatment of Crohn's disease and ulcerative colitis.

Background Information:

Crohn's Disease: According to the American Gastrointestinal Association clinical practice guidelines, evidence supports the use of methotrexate, corticosteroids, tumor necrosis factor inhibitors (TNFi) +/- immunomodulator, ustekinumab, or vedolizumab for induction of remission. Among the biologics, infliximab, adalimumab, ustekinumab, or vedolizumab are recommended or suggested over certolizumab for induction of remission. Evidence supports biologic agents, thiopurines, and methotrexate for maintenance of remission. Ustekinumab and vedolizumab are options for individuals with primary nonresponse to initial treatment with TNFi. Adalimumab, ustekinumab, or vedolizumab may be used in cases where an individual previously responded to infliximab and then lost response (secondary nonresponse).

Ulcerative Colitis: Both the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) Guidelines recommend or suggest TNFi, ozanimod, etrasimod, ustekinumab, guselkumab, mirikizumab, risankizumab, tofacitinib, upadacitinib, and vedolizumab for induction and maintenance of remission for patients with moderately to severely active UC. The AGA Guidelines provide recommendations for the positioning of advanced therapies. The AGA suggests using a higher efficacy medication (infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, guselkumab) or intermediate efficacy medication (golimumab, ustekinumab, tofacitinib, mirikizumab) medication rather than a lower efficacy medication (adalimumab) in individuals who are naïve to advanced therapies. For individuals who have previously been exposed to one or more advanced therapies, particularly TNFi, AGA suggests using a higher efficacy medication (tofacitinib, upadacitinib, ustekinumab) or an intermediate efficacy medication (mirikizumab, risankizumab, guselkumab) rather than a lower efficacy medication (adalimumab, vedolizumab, ozanimod, etrasimod).

Pediatric Use: Two publications (Conrad 2016, Singh 2016) describe the safety and efficacy of Entyvio (vedolizumab) in pediatric individuals with Crohn's disease or ulcerative colitis who had failed prior treatment with conventional therapy or one or more TNFi. Based on the available peer-reviewed literature and views of relevant medical specialists practicing in pediatrics and pediatric gastroenterology, the use of vedolizumab to induce or maintain remission may be considered a treatment option in a subset of the pediatric population 6 years of age or older with Crohn's disease or ulcerative colitis who are refractory to treatment with conventional drug therapy.

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Immune-checkpoint Inhibitor Therapy-Related Toxicity: The National Comprehensive Cancer Network (NCCN) guidelines on Management of Immunotherapy-Related Toxicities provide a 2A recommendation for the use of vedolizumab in the following indications secondary to immune checkpoint inhibitor therapy: moderate or severe diarrhea or colitis if colonoscopy or flexible sigmoidoscopy shows significant ulceration or extensive non-ulcerative inflammation; moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide; mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin. In patients with severe colitis, higher rates of refractory response to corticosteroids have been reported. Early introduction of vedolizumab can be considered to reduce recurrence. There is no high-quality data provided to support this use.

Hematopoietic Cell Transplantation: The National Comprehensive Cancer Network (NCCN) guidelines on Management of Hematopoietic Cell Transplantation provide a 2A recommendation for the use of vedolizumab in acute graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options. Therapy for steroid-refractory acute GVHD is often used in conjunction with the original immunosuppressive agent. There is no high-quality data provided to support this use.

According to NCCN, vedolizumab is recommended as a Category 2A option for the management of selected immune-mediated gastrointestinal toxicities. In immune checkpoint inhibitor-related toxicities, NCCN considers vedolizumab for moderate to severe esophagitis, gastritis, or duodenitis that does not improve with corticosteroids or budesonide; for persistent or progressive grade 1 diarrhea or colitis with positive lactoferrin or calprotectin; and for moderate to severe diarrhea or colitis when endoscopic or histologic findings support significant inflammation, including microscopic colitis. NCCN also notes that early introduction of vedolizumab may help reduce recurrence in patients with severe colitis. In addition, NCCN recommends vedolizumab as an adjunctive steroid-sparing agent for immune effector cell-associated enterocolitis specific to B-cell maturation antigen-directed CAR T-cell therapy in cases of steroid-refractory diarrhea or recurrent diarrhea during steroid taper, and as additional therapy for steroid-refractory acute graft-versus-host disease in conjunction with systemic corticosteroids.

Approved Indications

A. Moderately to severely active Crohn's Disease
B. Moderately to severely active Ulcerative Colitis

Other Uses

Per NCCN Guidelines (NCCN Category: 2A)

A. Management of Immunotherapy-Related Toxicities - Immune Checkpoint Inhibitor-Related Toxicities
B. Hematopoietic Cell Transplantation – Acute graft-versus-host disease
C. Steroid-sparing agent for immune effector cell-associated enterocolitis specific to B-cell maturation antigen-directed CAR T-cell therapy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Vedolizumab (Entyvio®)	MP-RX-FP28-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	7/22/2026
			Last Review Date: 7/22/2026	Frequently Revision: Annual

Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Vedolizumab (Entyvio®)

A. Criteria For Initial Approval Criteria For Initial Approval

I. Initial requests for *intravenous* Entyvio® (vedolizumab) may be approved for the following:

i. Crohn's disease (CD) when the following criteria are met:

A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe CD;

OR

ii. Ulcerative colitis (UC) when the following criteria are met:

A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe UC;

OR

iii. Immunotherapy-related toxicities when each of the following criteria are met (NCCN 2A):

A. Individual is undergoing immune checkpoint inhibitor therapy for a cancer diagnosis; **AND**
B. Individual is experiencing moderate (G2) to severe diarrhea (G3-4) or colitis as a result of immune checkpoint inhibitor treatment if colonoscopy or flexible sigmoidoscopy shows significant ulceration or extensive non-ulcerative inflammation; **OR**
C. Moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide as a result of immune checkpoint inhibitor treatment; **OR**
D. Mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin as a result of immune checkpoint inhibitor treatment;

OR

iv. Acute Graft-versus-host disease (GVHD) when each of the following criteria are met (NCCN 2A):

A. Individual has a diagnosis of steroid-refractory acute GVHD; **AND**
B. Individual is initiating vedolizumab in combination with systemic corticosteroids;

OR

Policy Name: Vedolizumab (Entyvio®)	Policy Number: MP-RX-FP28-23	Scope: ☒ MMM MA ☒ MMM MultiHealth	Origination Date: 11/30/2023	Effective Date: 7/22/2026
			Last Review Date: 7/22/2026	Frequently Revision: Annual

v. Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities - CAR T-Cell-Related Toxicities when each of the following criteria are met (NCCN 2A):

A. Individual has immune effector cell-associated enterocolitis specific to B-Cell Maturation Antigen-directed CAR T-Cell therapy; **AND**

B. Vedolizumab is being used as an adjunctive steroid-sparing agent; **AND**

C. Individual has *one* of the following:

1. Steroid-refractory diarrhea; **OR**
2. Recurrent diarrhea with steroid taper.

II. Initial requests for *subcutaneous* (vedolizumab) may be approved for the following:

i. Ulcerative colitis (UC) when the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe UC; **AND**

B. Individual has completed intravenous induction doses with Entyvio® and is using subcutaneous Entyvio® for maintenance therapy;

OR

C. Individual has been stabilized on intravenous Entyvio maintenance therapy and is switching to maintenance therapy with subcutaneous Entyvio®;

OR

ii. Crohn's disease (CD) when the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe CD; **AND**

B. Individual has completed intravenous induction doses with Entyvio and is using subcutaneous Entyvio® for maintenance therapy;

OR

C. Individual has been stabilized on intravenous Entyvio® maintenance therapy and is switching to maintenance therapy with subcutaneous Entyvio®.

B. Criteria For Continuation of Therapy

I. Continuation requests for *intravenous* Entyvio® (vedolizumab) may be approved if the following criteria are met:

i. Individual has been receiving and is maintained on a stable dose of intravenous Entyvio® (vedolizumab); **AND**

ii. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Vedolizumab (Entyvio®)	MP-RX-FP28-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	7/22/2026
			Last Review Date: 7/22/2026	Frequently Revision: Annual

II. Continuation requests for *subcutaneous* Entyvio® (vedolizumab) may be approved if the following criteria are met:

i. Individual has been receiving and is maintained on a stable dose of subcutaneous Entyvio® (vedolizumab); **AND**

ii. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. In combination with oral or topical JAK inhibitors, ozanimod, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, ustekinumab, abatacept, rituximab, or natalizumab; **OR**

ii. When the above criteria are not met and for all other indications.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Vedolizumab (Entyvio®)	MP-RX-FP28-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	7/22/2026
			Last Review Date: 7/22/2026	Frequently Revision: Annual

Limits or Restrictions:

A. Therapeutic Alternatives

This medical policy may be subject to Step Therapy. Please refer to the document published on the MMM Website: https://www.mmm-pr.com/planes-medicos/formulario-medicamentos

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosage	Limit
Entyvio® 300 mg/vial*^	• IV infusion: 300 mg IV at week 0, 2, and 6. ○ Patients may remain on Entyvio intravenous therapy or switch to subcutaneous injection after receiving two Entyvio intravenous doses administered at Week 0 and Week 2.	1 vial per 56 days (8 weeks)
Entyvio® (vedolizumab) 108 mg/ 0.68 mL prefilled syringe/pen	• Subcutaneous Injection: 108 mg subcutaneously once every two weeks.	2 syringes/pens every per 28 days

Exceptions

*Initiation of therapy: May approve up to 2 (two) additional single-use vials (300 mg/vial) in the first 6 weeks (42 days) of treatment.

^For CD or UC, may approve increased dosing, up to 1 vial (300 mg) every 4 weeks if the following criteria are met:

I. Individual has been treated with standard maintenance dosing (i.e. every 8 weeks) for at least 2 doses or 16 weeks; **AND**
II. The increased dosing is being prescribed by or in consultation with a gastroenterologist; **AND**
III. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber;

OR

IV. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber; **AND**
V. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
VI. Requested dosing does not exceed up to one vial (300 mg) every 4 weeks.

Initial approval duration for increased dosing for CD or UC: 16 weeks

^Requests for continued escalated dosing for CD or UC may be approved if the following criteria are met:

I. Requested dosing does not exceed up to one vial (300 mg) every 4 weeks; **AND**
II. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited

to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**

III. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**

IV. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for CD or UC: 1 year

^For CD or UC, Increased dosing may not be approved for the following:

I. Individual has had no response to Entyvio at standard maintenance dosing (i.e. every 8 weeks); **OR**

II. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
D89.810	Acute graft-versus-host disease [when specified as Entyvio intravenous for immunotherapy-related toxicity]
D89.812	Acute on chronic graft-versus-host disease [when specified as Entyvio intravenous for immunotherapy-related toxicity]
D89.813	Graft-versus-host disease, unspecified [when specified as Entyvio intravenous for immunotherapy-related toxicity]
T86.09	Other complications of bone marrow transplant [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K20.80	Other esophagitis without bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K20.81	Other esophagitis with bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K20.90 – K20.91	Esophagitis, unspecified without bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K20.91	Esophagitis, unspecified with bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K29.00	Acute gastritis without bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K29.01	Acute gastritis with bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K29.80	Duodenitis without bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K29.81	Duodenitis with bleeding [when specified as Entyvio intravenous for immunotherapy-related toxicity]
K29.70-K29.91	Gastritis, duodenitis, gastroduodenitis, unspecified [immune checkpoint inhibitor-related toxicity]
K50.00-K50.919	Crohn's disease (regional enteritis)
K51.00-K51.919	Ulcerative colitis
K52.1	Toxic gastroenteritis and colitis [when specified as Entyvio intravenous for immunotherapy-related toxicity]
R19.7	Diarrhea, unspecified [when specified as Entyvio intravenous for immunotherapy-related toxicity]
T45.AX5A-T45.AX5S	Adverse effect of immune checkpoint inhibitors and immunostimulant drugs
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XS	Complication of immune effector cellular therapy, sequela

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			Last Review Date: 7/22/2026	Frequently Revision: Annual

T80.89XA	Other complications following infusion, transfusion and therapeutic injection, initial encounter
T80.89XS	Other complications following infusion, transfusion and therapeutic injection, sequela

HCPCS Codes:

Codes	Description
J3380	Injection, vedolizumab, intravenous,1 mg [Entyvio®]
J3590	Unclassified biologics (when specified as injection, vedolizumab, 108 mg/0.68 mL prefilled syringe/pen] [Entyvio SC®].
C9399	Unclassified drugs or biologicals [when specified as Entyvio SC (vedolizumab subcutaneous)]

Reference Information:

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
5. Feuerstein JD, Ho EY, Shmidt E et al. American Gastroenterological Association Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology 2021; 160:2496-2508.
6. Feuerstein JD, Issacs KL, Schneider Y, et al. American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
7. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. Am J Gastroenterol 2018; 113:481–517.
8. Rubin DT, Ananthakrishnan AN, Siegel CA et al. American College of Gastroenterology Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114:384-413.
9. Conrad MA, Stein RE, Maxwell EC, et al. Vedolizumab therapy in severe pediatric inflammatory bowel disease. Inflamm Bowel Dis. 2016; 22(10):2425-2431.
10. Singh N, Rabizadeh S, Jossen J, et al. Multi-center experience of vedolizumab effectiveness in pediatric inflammatory bowel disease. Inflamm Bowel Dis. 2016; 22(9):2121-2126
11. NCCN Clinical Practice Guidelines in Oncology™. © 2026 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on May 20, 2026.
    a. Management of Immunotherapy-related Toxicities. V1.2026. Revised October 23, 2025
    b. Hematopoietic Cell Transplantation (HCT). V2.2026. Revised April 3, 2026.
    c. Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities. Version 2.2026. Revised November 11, 2025.
12. Takeda Pharmaceuticals U.S.A., Inc. (2026). ENTYVIO® (vedolizumab) for injection, for intravenous use; ENTYVIO® (vedolizumab) injection, for subcutaneous use; ENTYVIO® PEN (vedolizumab) injection, for subcutaneous use: Prescribing information. Revised March 2026. Accessed May 20, 2026.

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			Last Review Date: **7/22/2026**	**Frequently Revision:** **Annual**

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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			Last Review Date: 7/22/2026	**Frequently Revision:** Annual

Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Ulcerative Colitis description in the Background Information and added NCCN Category 2A recommendations. Removed prerequisite conventional therapy requirements for CD and UC; updated uses in immunotherapy-related toxicities per NCCN. Incorporated the NCCN Category 2A recommendation for vedolizumab as an adjunctive steroid-sparing agent for immune effector cell-associated enterocolitis specific to B-cell maturation antigen-directed CAR T-cell therapy Added recommended dosages and updated escalated dosing continued approval duration to 1 year. Updated may not approve criteria; removed infection and progressive multifocal leukoencephalopathy exclusions. Coding Reviewed: Updated description for HCPCS J3380 and J3590 and added C9399 for Entyvio SC. Added ICD-10-CM K20.90-K20.91, K29.70-K29.91, T45.AX5A-T45.AX5S and T80.82XA, T80.82XS, T80.89XA, and T80.89XS. Wording and formatting changes. Updated reference information and incorporated new policy template.	7/13/2026	7/22/2026
Annual Review	Added Background Information for Hematopoietic Cell Transplantation indication per NCCN Guidelines. Updated Background information of Immune Checkpoint Inhibitor-Related Toxicities per new NCCN Guidelines. Updated "Other use" section with NCCN indications. Coding Reviewed: Added 1CD-10-CM K20.80, K20.81, K20.90, K20.91, K29.00, K29.01, K29.80, K29.81, D89.810, D89.812, D89.813, T86.09. Added Clinical Criteria for new Acute Graft-versus-host disease (GVHD) indication per NCCN. Added Clinical Criteria for new Indications of Immune Checkpoint Inhibitor-Related Toxicities: moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide; mild diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin; moderate to severe diarrhea or colitis if colonoscopy or flexible sigmoidoscopy shows significant ulceration or extensive non-ulcerative inflammation. Updated subcutaneous quantity limit to monthly limit. Added etrasimod combination to Conditions not covered section. Added NCCN Guideline to the "Reference Information" section. Formatting and wording changes.	8/25/2025	9/8/2025
Annual Review	Update quantity limit table. Coding Reviewed: Added ICD-10-CM K52.1, R19.7 to Entyvio intravenous. Update clinical criteria for new Crohn's Disease indication for subcutaneous dosage form. Coding Reviewed: Added HCPCS code J3590 (when specified as Entyvio SC). Separate continuation criteria for subcutaneous and intravenous formulations; wording and formatting updates.	11/18/2024	12/27/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023