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Last P&T Approval/Version: 07/31/2024
Next Review Due By: 10/2024
Policy Number: C6773-A

Entyvio (vedolizumab)

PRODUCTS AFFECTED

Entyvio (vedolizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Crohn's Disease, Ulcerative Colitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:
1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening*

or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
AND
3. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections
AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

B. CROHN'S DISEASE:

1. Documentation of a diagnosis of Crohn's Disease
AND
2. Member has one or more high risk feature:
   i. Diagnosis at a younger age (<30 years old)
   ii. History of active or recent tobacco use
   iii. Elevated C-reactive protein and/or fecal calprotectin levels
   iv. Deep ulcers on colonoscopy
   v. Long segments of small and/or large bowel involvement
   vi. Perianal disease
   vii. Extra-intestinal manifestations
   viii. History of bowel resections
   AND
3. (a) Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (> 3 months) of ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate) up to maximally indicated doses
   OR
   (b) Prescriber provides documented medical justification that supports the inability to use immunomodulators
   i. Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
   ii. High-risk factors for intestinal complications may include: Initial extensive ileal, ileocolonic, or proximal GI involvement, Initial extensive perianal/severe rectal disease, Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas), Deep

ulcerations, Penetrating, stricturing or stenosis disease and/or phenotype, Intestinal obstruction or abscess

iii. High risk factors for postoperative recurrence may include: Less than 10 years duration between time of diagnosis and surgery, Disease location in the ileum and colon, Perianal fistula, Prior history of surgical resection, Use of corticosteroids prior to surgery

AND

4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

C. ULCERATIVE COLITIS:

1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
   AND
2. (a) Documentation of treatment failure, serious side effects or clinical contraindication to a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently. *NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion]) also counts as a trial of one systemic agent for UC*
   OR
   b) The member has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® (hydrocortisone enema, generics)], or topical mesalamine
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 5 months [4 doses (at zero, two, and six weeks then once every eight- weeks)]

*Discontinue therapy if no evidence of therapeutic benefit by week 14,
Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For TX Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified gastroenterologist or colorectal surgeon. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age or older

QUANTITY:
Intravenous dosing:
300 mg IV at weeks 0, 2 and 6 and then every 8 weeks thereafter
When requests for off-label dosing, dose escalation, or dose intensification are received, requests will be reviewed for evidence that current or standard dosing is not adequate to produce a therapeutic level of drug (e.g., pharmacokinetic failure), clinical failure or significant loss of response is present, and the requested dosing is established as safe and effective for the condition. There are certain situations where no additional amount of drug is likely to produce or recapture clinical effect because the condition is no longer responsive to the drug (e.g., pharmacodynamic failure) or the drug cannot reach the site of activity at sufficient levels. The following items will assist reviewers in determining if the requested dosing is medically necessary:

- *FDA or compendium-supported dosing and therapeutic monitoring recommendations for the drug*
- *Member claims/adherence history*
- *Clinical documentation of the member's response to current or standard dosing regimens (disease activity indices if commonly used in clinical practice or documentation to approximate them may be necessary to demonstrate the response)*
- *In conjunction with documented clinical failure or loss of response or wearing off of effect, test results that demonstrate failure of current or standard dosing to reach established treatment thresholds (e.g., established therapeutic monitoring recommendations)*
- *If applicable, documentation showing the member does not have conditions which make achieving a therapeutic level of drug unlikely even with dose intensification (e.g., dose intensification may be futile due to the presence of anti-drug antibodies, protein losing enteropathy, nephrotic syndrome, severe drug excretion or malabsorption issues, etc.)*
- *In certain situations, documentation or peer-to-peer determination that re-induction cannot be tried to recapture response as an alternative to long term dose escalation or intensification*

Subcutaneous formulation:
Following the first two IV doses (week 0 and week 2), may switch to SQ injection at week 6. Starting at week 6: 108mg subcutaneously every 2 weeks
Switching during maintenance IV dosing (member with clinical response or remission beyond week 6): administer 108mg subcutaneously in place of the next scheduled IV infusion and every 2 weeks thereafter

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Entyvio (vedolizumab). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous, Subcutaneous

DRUG CLASS:
Integrin Receptor Antagonists

FDA-APPROVED USES:
Indicated in adults for the treatment of moderately to severely active ulcerative colitis, moderately to severely active Crohn's disease.

COMPENDIAL APPROVED OFF-LABELED USES:
Immunotherapy related diarrhea or colitis (refer to Molina Off-Label policy)

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

APPENDIX 2:
Crohn's Disease Activity Index (CDAI): frequently used to assess disease severity; scores ranging from 0 to over 600, based on a diary of symptoms kept by the member for 7 days, general well- being, deviation of weight, features of extraintestinal disease, use of antidiarrheal medications, presence of abdominal mass, and hematocrit levels.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Inflammatory bowel disease (IBD) is a chronic inflammatory disorder of the gastrointestinal tract of unknown etiology and characterized by a chronic idiopathic inflammation of the intestine and consists of two main forms, ulcerative colitis (UC) and Crohn's disease (CD). While UC and CD have similar clinical presentations, they differ in the body areas affected. CD is characterized by deeper and more erratic inflammation that can occur throughout the entire digestive tract. In UC, inflammation is continuous and widespread and disturbs

the superficial mucosal layer of the large intestine or the colon.

Crohn's disease (CD) is a chronic, inflammatory, multisystem disorder of unknown etiology with genetic, immunologic, and environmental influences. CD involves any area of the gastrointestinal tract(GIT) from the oral cavity to the anus, but it is limited primarily to the colon with or without small- intestine disease. Moreover, the inflammation in CD is often described as transmural, damaging each mucosal layer of the GIT, and noncontinuous. Therapy for CD includes medical therapy with pharmacologic agents consisting of 5-aminosalicylates (5-ASA), antibiotics, corticosteroids, immunomodulators, and biologics. Surgery is reserved for patients who are refractory to medical therapy. The key symptoms of CD include abdominal pain, diarrhea, and fatigue. Weight loss, fever, growth failure, anemia, recurrent fistulas, or extraintestinal manifestations (e.g., arthritis, iritis) can also occur. There is no single laboratory test that can make an unequivocal diagnosis of CD.

Ulcerative colitis (UC) is a chronic inflammatory condition characterized by relapsing and remitting episodes of inflammation that involves the rectum and colon. The definitive etiology of ulcerative colitis is unknown, but suspected causes are similar to those of CD. Inflammation can be mild, moderate, or severe. UC is limited to the superficial mucosa of the colon. UC more commonly involves the entire colon in children than in adults, who more commonly will have limited left-sided disease. The goals of treatment are to control the acute attacks, prevent recurrent attacks and promote healing of the colon. Severe attacks may require hospitalization. Generally, first-line treatment of UC includes corticosteroids, 6- mercaptopurine and azathioprine.

The anti-tumor necrosis factor (anti-TNF) agents (infliximab, adalimumab, and certolizumab pegol) are effective for treatment of patients with CD who respond inadequately to treatment with corticosteroids, thiopurines, and methotrexate. Anti-TNF agents have rapid onset of effect, with benefit often noted within 2 weeks of initiating therapy. Anti–TNF agents are reserved for moderate to severe disease refractory to corticosteroids and immunomodulators in both CD and UC. Infliximab and adalimumab carry approvals for both CD and UC, though certolizumab pegol is approved only for CD.

Other monoclonal antibodies approved for IBD are the integrin inhibitors. Vedolizumab, an α4 β7integrin inhibitor, is approved for both CD and UC, and natalizumab, an α4 integrin inhibitor, is approved for use in CD. These drugs are reserved for patients nonresponsive to conventional therapies, including TNF inhibitors, and carry a risk of PML.

Vedolizumab (Entyvio), a humanized monoclonal antibody, works as an antagonist of the α4β7 integrin receptor that ultimately blocks T cell migration within the gastrointestinal tract. Vedolizumab is a gut-selective immunosuppressive biologic and humanized monoclonal antibody that is being developed to specifically antagonize the α4β7 integrin. With this target, the drug is designed to inhibit the binding of alpha4beta7 integrin to intestinal mucosal addressing cell adhesion molecule 1 (MAdCAM-1) and fibronectin, but not vascular cell adhesion molecule 1 (VCAM-1). By inhibiting alpha4beta7 integrin, vedolizumab has the potential to limit the ability of some white blood cells to permeate gut tissues.

American College of Gastroenterology (ACG)

In March 2018, the ACG released an updated guideline on managing CD in adult patients. It includes preferable approaches on diagnosis, disease modifiers, and medical therapy for the various disease severities.

Nonsteroidal anti-inflammatory drugs (NSAIDs) may exacerbate disease activity and should be avoided when possible in patients with Crohn disease.

Sulfasalazine is effective for treating symptoms of colonic Crohn disease that is mild to moderately active and can be used as treatment for this member population.

For patients with low risk of progression, treatment of active symptoms with antidiarrheals, other nonspecific medications, and dietary manipulation, along with careful observation for inadequate symptom relief, worsening inflammation, or disease progression, is acceptable.

Oral corticosteroids are effective and can be employed for short-term use in alleviating signs and symptoms of moderately to severely active Crohn disease. Thiopurines (azathioprine, 6- mercaptopurine) are effective

and should be considered for use for steroid sparing in Crohn disease. Azathioprine and 6- mercaptopurine are effective therapies and should be considered for treatment of patients with Crohn disease for maintenance of remission. Methotrexate (up to 25 mg once weekly intramuscularly [IM] or subcutaneously [SC]) is effective and should be considered for use in alleviating signs and symptoms in patients with steroid-dependent Crohn disease and for maintaining remission.

Anti–tumor necrosis factor (anti-TNF) agents (infliximab, adalimumab, certolizumab pegol) should be used to treat Crohn disease that is resistant to treatment with corticosteroids.

Anti-TNF agents should be given for Crohn disease refractory to thiopurines or methotrexate. Combination therapy of infliximab with immunomodulators (thiopurines) is more effective than treatment with either immunomodulators alone or infliximab alone in patients who are naive to those agents.

For patients with moderately to severely active Crohn disease and objective evidence of active disease, anti-integrin therapy (with vedolizumab) with or without an immunomodulator is more effective than placebo and should be considered for use in induction of symptomatic remission inpatients with Crohn disease.

Natalizumab is more effective than placebo and should be considered for use in induction of symptomatic response and remission in patients with active Crohn disease.

Natalizumab should be used for maintenance of natalizumab-induced remission of Crohn disease only if serum antibody to John Cunningham (JC) virus is negative. Testing for anti-JC virus antibody should be repeated every 6 months and treatment stopped if the result is positive. Ustekinumab should be given for moderate to severe Crohn disease patients who failed previous treatment with corticosteroids, thiopurines, methotrexate, or anti-TNF inhibitors or who have had no prior exposure to anti-TNF inhibitors.

Intravenous corticosteroids should be used to treat severe or fulminant Crohn disease.

Anti-TNF agents (infliximab, adalimumab, certolizumab pegol) can be considered to treat severely active Crohn disease.

Infliximab may be administered to treat fulminant Crohn disease. Infliximab is effective and should be considered in treating perianal fistulas in Crohn disease. Infliximab may be effective and should be considered in treating enterocutaneous and rectovaginal fistulas in Crohn disease.

Adalimumab and certolizumab pegol may be effective and should be considered in treating perianal fistulas in Crohn disease.

Thiopurines (azathioprine, 6-mercaptopurine) may be effective and should be considered in treating fistulizing Crohn disease.

Once remission is induced with corticosteroids, a thiopurine or methotrexate should be considered. Anti-TNF therapy, specifically infliximab, adalimumab, and certolizumab pegol, should be used to maintain remission of anti-TNF–induced remission.

Anti-TNF monotherapy is effective at maintaining anti-TNF–induced remission, but because of the potential for immunogenicity and loss of response, combination with azathioprine/6- mercaptopurine or methotrexate should be considered.

Imidazole antibiotics (metronidazole and ornidazole) at doses between 1 and 2 g/day can be used after small intestinal resection in Crohn disease patients to prevent recurrence.

ACG Clinical Guideline: Ulcerative Colitis in Adults

The management of ulcerative colitis (UC) has changed since the last guideline was published in 2010. The recommendations in the current update are based on the quality of evidence using GRADE (Grading of Recommendations Assessment, Development, and Evaluation) methodology. An updated clinical guideline on the management of UC shifts the focus from symptom-based treatment to both symptom management and mucosal healing. New tests, including those based on serum drug levels and fecal calprotectin, as well as newer FDA-approved therapies, including budesonide, vedolizumab, and tofacitinib. Key recommendations include:

Treat patients with UC to achieve mucosal healing, increase the likelihood of sustained steroid- free remission, and prevent hospitalizations and surgery.

In patients with moderately active UC, use non-systemic corticosteroids, such as budesonide MMX, before systemic therapy.

In patients with moderately to severely active UC, use vedolizumab to induce remission.

In patients with moderately to severely active UC, use tofacitinib (10 mg orally twice daily for 8 weeks) to

induce remission.
Do not defer colectomy because of exposure to infliximab and cyclosporine, as these agents do not increase the risk for postoperative complications.
In patients with acute severe UC and concomitant *Clostridium difficile* infection, use vancomycin instead of metronidazole.
Perform surveillance colonoscopies in patients with UC at 1- to 3-year intervals, based on the combined risk factors for colorectal cancer in UC and the findings on previous colonoscopy.

AGA Guidelines Moderate to Severe Ulcerative Colitis
Recommendations from the recent 2020 guideline update include:

- In adult outpatients with moderate to severe UC who are naïve to biologic agents, the AGA suggests using infliximab or vedolizumab rather than adalimumab, for induction of remission.
- Updated FDA recommendations (July 26, 2019) on indications for use of tofacitinib in UC recommends its use only after failure of or intolerance to TNF-a antagonists.
- In adult outpatients with moderate to severe UC who have previously been exposed to infliximab, particularly those with primary nonresponse, the AGA suggests using ustekinumab or tofacitinib rather than vedolizumab or adalimumab for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests against using methotrexate monotherapy for induction or maintenance of remission.
- In adult outpatients with active moderate to severe UC, the AGA suggests using biologic monotherapy (TNF-a antagonists, vedolizumab, or ustekinumab) or tofacitinib rather than thiopurine monotherapy for induction of remission.
- In adult outpatients with moderate to severe UC, the AGA suggests combining TNF-a antagonists, vedolizumab or ustekinumab with thiopurines or methotrexate rather than biologic monotherapy.
- In adult outpatients with moderate to severe UC who have achieved remission with biologic agents and/or immunomodulators or tofacitinib, the AGA suggests against continuing 5-ASA for induction and maintenance of remission.

VARSITY Trial: Ulcerative Colitis in Adults
Entyvio and Humira were compared in adults with moderately to severely active UC in a Phase 3b double-blind, double-dummy, randomized trial. Previous exposure to a tumor necrosis factor inhibitor other than adalimumab was allowed in up to 25% of patients. At week 52, clinical remission was observed in a higher percentage of patients in the Entyvio group than in the Humira group (31.3% vs. 22.5%; difference, 8.8 percentage points; 95% confidence interval [CI], 2.5 to 15.0; P=0.006), as was endoscopic improvement (39.7% vs. 27.7%; difference, 11.9 percentage points; 95% CI, 5.3 to 18.5; P<0.001). This data and the current AGA guidelines that suggest using infliximab or Entyvio rather than adalimumab, for induction of remission, show Entyvio has emerged as a first-line agent for the management of moderately to severely active UC.

Immunotherapy related diarrhea or colitis
Recent NCCN guidelines include use of vedolizumab for moderate and severe diarrhea and colitis (grade 2 and above) related to immune checkpoint inhibitor therapy. If no response to treatment with steroids, consider adding infliximab or vedolizumab. For infliximab and/or vedolizumab refractory colitis, consider tofacitinib or ustekinumab. Refer to NCCN guidelines for management of immunotherapy related toxicities.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Entyvio (vedolizumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Entyvio (vedolizumab) include: patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients (such as dyspnea, bronchospasm, urticaria, flushing, rash and increased heart rate).
Exclusions for coverage include, but are not limited to: Combination with another biologic agent for an inflammatory condition [e.g., Actemra (tocilizumab), Enbrel (etanercept), Kineret (anakinra), Orencia

(abatacept), Remicade (infliximab), Rituxan (rituximab), Simponi (golimumab)]; Currently diagnosed with, or history of, progressive multifocal leukoencephalopathy (PML)

OTHER SPECIAL CONSIDERATIONS:

Entyvio IV should be administered by a healthcare provider. Entyvio SQ may be self injected or caregiver may inject after proper training on correct subcutaneous injection technique.

If treatment with subcutaneous ENTYVIO is interrupted or if a scheduled dose(s) of subcutaneous ENTYVIO is missed, inject the next subcutaneous dose as soon as possible and then every 2 weeks thereafter.

CODING/BILLING INFORMATION

HCPCS CODE	DESCRIPTION
J3380	Injection, vedolizumab, 1mg

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

AVAILABLE DOSAGE FORMS:

Entyvio SOLR 300MG single-dose vial
Entyvio SOPN 108MG/0.68ML single dose prefilled pen

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Duration of Approval Quantity Place of Administration Route of Administration References	Q3 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Background Other Special Considerations Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Place of Administration FDA-Approved Uses Compendial Approved Off-Labeled Uses Background Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file