Drug and Biologic Coverage Policy

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Vedolizumab

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Immunomodulators – Oral and Subcutaneous (Employer Group Benefit Plans)
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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

Vedolizumab (Entyvio®) is considered medically necessary when both of the following criteria are met:

- Individual is 18 years of age or older
- Diagnosis of either of the following:
  - Moderate to severe Crohn's disease and BOTH of the following:
    - ONE of the following†:
      - Documented failure or inadequate response, contraindication per FDA label, intolerance, not a candidate for a corticosteroid OR taken concurrently with a corticosteroid (for example, prednisone, methylprednisolone)
      - Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for one conventional systemic therapy OR taken concurrently with a conventional systemic therapy (for example, azathioprine, 6-mercaptopurine, methotrexate [MTX])

      † *Note: An exception to the requirement can be made if the individual has already tried a biologic. These individuals are not required to "step back" and a try a steroid or a conventional agent.*
    - Prescribed by, or in consultation with a gastroenterologist or a prescriber who specializes in Crohn's disease

- Ulcerative colitis and BOTH of the following:
  - Documented failure or inadequate response, contraindication per FDA label, intolerance, or not a candidate for at least ONE conventional therapy (for example, aminosalicylate, corticosteroids or immunosuppressants) †

    † *Note: An exception to this requirement can be made if the individual has already tried a biologic.. These individuals are not required to "step back" and try a conventional agent.*
  - Prescribed by or in consultation with a gastroenterologist or a prescriber who specializes in ulcerative colitis

Initial authorization is up to 12 months.

Vedolizumab (Entyvio) is considered medically necessary for continued use when the individual has had a positive response to Entyvio.

Reauthorization for up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Vedolizumab (Entyvio) is considered experimental, investigational or unproven for ANY other use including the following:

- Concomitant use with any other biologic including all non-tumor necrosis factor (non-TNF) biologics, anti-TNF biologics, or oral immunomodulatory agents (for example, Otezla or Xeljanz/ Xeljanz XR)

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

Adult Ulcerative Colitis

Entyvio (vedolizumab) is indicated for:

- inducing and maintaining clinical response,
- inducing and maintaining clinical remission,
- improving the endoscopic appearance of the mucosa, and
- achieving corticosteroid-free remission

in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Adult Crohn's Disease

Entyvio (vedolizumab) is indicated for:

- achieving clinical response,
- achieving clinical remission, and
- achieving corticosteroid-free remission

in adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Recommended Dosing

FDA Recommended Dosing

Administer Entyvio as an intravenous infusion over 30 minutes. Do not administer as an intravenous push or bolus. Entyvio should be administered by a healthcare professional prepared to manage hypersensitivity reactions including anaphylaxis, if they occur. Appropriate monitoring and medical support measures should be available for immediate use. Observe patients during infusion and until the infusion is complete. Prior to initiating treatment with Entyvio, all patients should be brought up to date with all immunizations according to current immunization guidelines.

Dosage in Adults with Ulcerative Colitis or Crohn's Disease
The recommended dosage of Entyvio in adults with ulcerative colitis or Crohn's disease is 300 mg administered by intravenous infusion at zero, two and six weeks and then every eight weeks thereafter. Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.

Background

Pharmacology
Vedolizumab is a monoclonal antibody directed against alpha-4-beta-7 integrin, an adhesion molecule expressed on T-cells that migrate to the gut. Alpha-4-beta-7 is required for leukocyte migration into inflamed GI tissues. Vedolizumab selectively inhibits alpha-4-beta-7 integrin without affecting alpha-4-beta-1 integrin, making it GI-specific.

Professional Societies/Organizations
Crohn's Disease
American College of Gastroenterology (ACG)
The American College of Gastroenterology (ACG) has updated guidelines (2018) for Crohn's disease. Entyvio is among the treatment recommendations for treatment of patients with moderate to severe disease or moderate to high risk disease (for induction of remission as well as maintenance of this remission). (Lichtenstein, 2018)

Ulcerative Colitis
American College of Gastroenterology (ACG)
Updated ACG guidelines for UC (2019) note that the following agents can be used for induction of remission in moderately to severely active disease: Uceris (budesonide extended-release tablets); oral or intravenous systemic corticosteroids, Entyvio, Xeljanz, or TNFis (adalimumab, Simponi SC, infliximab).[3] The Toronto Consensus Guidelines (2015) also address use of Entyvio in UC.[4] These guidelines note that Entyvio is a treatment option for patients with moderate to severe active UC who have failed corticosteroids, thiopurines, or TNFis. However, there are no data regarding treatment strategies following failure of Entyvio. (Bressler, 2015)

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative:
No recommendations are available for vedolizumab, Crohn's disease, or ulcerative colitis.

Centers for Medicare & Medicaid Services - National Coverage Determinations (NCDs)
There are no CMS National Coverage Determinations for vedolizumab.

Other Uses with Supportive Evidence
AHFS Drug Information 2019 Edition does not support any off-label uses of vedolizumab.

Coding/Billing Information

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.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J3380	Injection, vedolizumab, 1 mg

References

1. Bressler B, Marshall JK, Bernstein CN, et al. Clinical practice guidelines for the medical management of nonhospitalized ulcerative colitis: the Toronto consensus. *Gastroenterology*. 2015;148(5):1035-1058.
2. Entyvio™ for intravenous injection [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2019.
3. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.doi:10.1038/ajg.2018.27
4. McEvoy GK, ed. AHFS 2019 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc. 2019.