Pharmacy Drug Policy & Procedure

Policy Name:	Entyvio (vedolizumab)	Policy #:	2262P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Entyvio.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Entyvio under the specialty medical benefit when the criteria below have been met.

Criteria

1. Coverage Criteria for Ulcerative Colitis

1.1 See Ulcerative Colitis Immunomodulator Therapies policy

2. Coverage Criteria for Ulcerative Proctitis

2.1 Ordered by or in consultation with a gastroenterologist (stomach doctor)

2.2 Documented failure, intolerance, or contraindication to topical 5-ASA rectal suppositories and enemas

2.3 Documented failure, intolerance, or contraindication to systemic conventional therapy (mesalamine, sulfasalazine, prednisone, cyclosporine),

2.4 Documented failure, intolerance, or contraindication to a covered adalimumab biosimilar

- Covered adalimumab biosimilars (as of 7/1/2024) include: Amjevita (72511040001, 72511040002, 55513039901, 555130479**, 555130481**, 555130482**), Hadlima (78206018701, 78206018401, 78206018601, and 78206018301), Adalimumab-adaz (61314032720 and 61314032764), and Adalimumab-adbm (005970545**, 00597055580, 00597056520, 005970575**, 00597058589, and 00597059520)

3. Coverage Criteria for Crohn's Disease

3.1 See Crohn's Disease Immunomodulator Therapies policy

4. Approval Period

4.1 Initial Authorization will be placed for 12 months

4.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

5. Exclusions

5.1 Entyvio (vedolizumab) is not considered medically necessary for an individual with any of the following:

- In combination with a TNF antagonist (etanercept, adalimumab)
- In combination with a non-TNF antagonist immunomodulatory drug, such as natalizumab (Tysabri)
- Active, serious infection or a history of recurrent infections
- New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML).
- Concurrent treatment with Tacrolimus (Topical): May enhance the adverse/toxic effect of Immunosuppressants (Risk X)

- Concurrent treatment with Pimecrolimus: May enhance the adverse/toxic effect of Immunosuppressants (Risk X)
- Signs or symptoms of jaundice or significant liver injury
- Lack of therapeutic benefit after week 14 of therapy
- Off-label (non-FDA Approved) dosing frequencies

CPT Codes	
96365-96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)

HCPCS Codes	
J3380	Injection, vedolizumab, 1mg [Entyvio]

References

1. Entyvio (vedolizumab) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA Inc; September 2023.
2. Abdulrazeg O, Li B, Epstein J; Guideline Committee. Management of ulcerative colitis: summary of updated NICE guidance. BMJ. 2019 Oct 28;367:l5897.
3. Feuerstein JD, Ho EY, Shmidt E, et al; American Gastroenterological Association Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021 Jun;160(7):2496-2508.
4. Lightner A, Vogel J, Carmichael J, Keller D, et al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Surgical Management of Crohn’s Disease. Diseases of the Colon & Rectum: August 2020 - Volume 63 - Issue 8 - p 1028-1052
5. Lichtenstein G, Loftus E, Isaacs K, et al. Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018 Apr;113(4):481-517.

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DISCLAIMER
This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.