

Highmark Medicare Advantage Medical Policy- PA, DE, WV, NY

Medical Policy: I-129-01²³
Topic (or Title): Vedolizumab (Entyvio)
Section: Injections
Effective Date: ~~November 25, 2024~~ October 13, 2025
Issued Date: ~~November 25, 2024~~ October 13, 2025
Last Revision Date: August 2024⁴⁵

Vedolizumab (Entyvio®) is a monoclonal antibody and integrin receptor antagonist used for the treatment of moderately to severely active Crohn's disease (CD) and ulcerative colitis (UC) in adults. Vedolizumab (Entyvio) reduces chronically inflamed gastrointestinal tissue associated with UC/CD by binding to the $\alpha 4\beta 7$ integrin receptor and inhibiting its interaction with mucosal addressin cell adhesion molecule-1 (MAdCAM-1).

Policy Position

Approved Use

Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective when used for indications specified on the labeling. Please refer to product specific labeling for approved indications. Coverage is also dictated by National Coverage Determinations or the appropriate Local Coverage Determinations

Unlabeled Use

Vedolizumab (Entyvio) may be considered medically necessary for treatment of **ANY** of the following:

- Micromedex DrugDex Compendium® Class I, Class IIa, or Class IIb indications; **or**
 - Use supported in the American Hospital Formulary Service Drug Information (AHFS-DI) ;
- or**
- Use supported in Clinical Pharmacology™ Compendium; **or**
 - Indication listed in Lexi-Drugs as "Use: off-Label" and rated as "Evidence Level A".

Vedolizumab (Entyvio) is considered not medically necessary for **ANY** of the following:

- Micromedex DrugDex Compendium® Class III indications; **or**
- Narrative text in AHFS or Clinical Pharmacology is "not supportive"; **or**
- Indication listed in Lexi-Drugs as "Use: Unsupported"; **or**
- Indication not FDA-labeled and not listed in any compendia.

Vedolizumab (Entyvio) may be considered medically necessary for treatment of any of the current category 1, 2A, or 2B NCCN recommendations.

The use of vedolizumab (Entyvio) not meeting the criteria as indicated in this policy is considered experimental/investigational, and therefore, not medically necessary.

Procedure Codes

J3380

Diagnosis Codes
Covered Diagnosis Codes for Procedure Code J3380

D89.810	D89.812	D89.813	<u>K20.80</u>	<u>K20.81</u>	<u>K20.90</u>	<u>K20.91</u>
<u>K29.00</u>	<u>K29.01</u>	<u>K29.80</u>	<u>K29.81</u>	K50.00	K50.011	K50.012
K50.013	K50.014	K50.018	K50.019	K50.10	K50.111	K50.112
K50.113	K50.114	K50.118	K50.119	K50.80	K50.811	K50.812
K50.813	K50.814	K50.818	K50.819	K50.90	K50.911	K50.912
K50.913	K50.914	K50.918	K50.919	K51.00	K51.011	K51.012
K51.013	K51.014	K51.018	K51.019	K51.20	K51.211	K51.212
K51.213	K51.214	K51.218	K51.219	K51.30	K51.311	K51.312
K51.313	K51.314	K51.318	K51.319	K51.40	K51.411	K51.412
K51.413	K51.414	K51.418	K51.419	K51.50	K51.511	K51.512
K51.513	K51.514	K51.518	K51.519	K51.80	K51.811	K51.812
K51.813	K51.814	K51.818	K51.819	K51.90	K51.911	K51.912
K51.913	K51.914	K51.918	K51.919	K52.1		

Note: If an individual has already had a trial of at least one biologic agent, they are not required to “step back” and try a non-biologic agent.

NOTE: In addition to the above criteria, product specific dosage and/or frequency limits may apply in accordance with the U.S. Food and Drug Administration (FDA)-approved product prescribing information, national compendia, Centers for Medicare and Medicaid Services (CMS) and other peer reviewed resources or evidence-based guidelines. Highmark may deny, in full or in part, reimbursement for utilization that does not fall within the applicable dosage and/or frequency limits.

The policy position applies to all Medicare Advantage lines of business

Links

- [Link to References](#)
- [Link to Provider Resource Center for the Medical Policy Update](#)

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect Highmark's reimbursement and coverage guidelines. Coverage for

services may vary for individual members, based on the terms of the benefit contract, and subject to the applicable laws of your state.

Highmark retains the right to review and update its medical policy guidelines at its sole discretion. These guidelines are the proprietary information of Highmark. Any sale, copying or dissemination of the medical policies is prohibited; however, limited copying of medical policies is permitted for individual use.

Discrimination is Against the Law

The Claims Administrator/Insurer complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. The Claims Administrator/Insurer does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex. The Claims Administrator/ Insurer:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that the Claims Administrator/Insurer has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: Civil Rights Coordinator, P.O. Box 22492, Pittsburgh, PA 15222, Phone: 1-866-286-8295, TTY: 711, Fax: 412-544-2475, email: CivilRightsCoordinator@highmarkhealth.org. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Insurance or benefit/claims administration may be provided by Highmark, Highmark Choice Company, Highmark Coverage Advantage, Highmark Health Insurance Company, First Priority Life Insurance Company, First Priority Health, Highmark Benefits Group, Highmark Select Resources, Highmark Senior Solutions Company or Highmark Senior Health Company, all of which are independent licensees of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield plans.

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call the number on the back of your ID card (TTY: 711).

ATENCIÓN: Si usted habla español, servicios de asistencia lingüística, de forma gratuita, están disponibles para usted. Llame al número en la parte posterior de su tarjeta de identificación (TTY: 711).

请注意：如果您说中文，可向您提供免费语言协助服务。

请拨打您的身份证背面的号码（TTY： 711）。

CHÚ Ý: Nếu quý vị nói tiếng Việt, chúng tôi cung cấp dịch vụ hỗ trợ ngôn ngữ miễn phí cho quý vị. Xin gọi số điện thoại ở mặt sau thẻ ID của quý vị (TTY: 711).

알림: 한국어를 사용하시는 분들을 위해 무료 통역이 제공됩니다. ID 카드 뒷면에 있는 번호로 전화하십시오 (TTY: 711).

ATENSYON: Kung nagsasalita ka ng Tagalog, may makukuha kang mga libreng serbisyong tulong sa wika. Tawagan ang numero sa likod ng iyong ID card (TTY: 711).

ВНИМАНИЕ: Если вы говорите по-русски, вы можете воспользоваться бесплатными услугами языковой поддержки. Позвоните по номеру, указанному на обороте вашей идентификационной карты (номер для текст-телефонных устройств (TTY): 711).

تنبيه: إذا كنت تتحدث اللغة العربية، فهناك خدمات المساعدة في اللغة المجانية متاحة لك. اتصل بالرقم الموجود خلف بطاقة هويتك (جهاز الاتصال لذوي صعوبات السمع والنطق: 711).

ATTENTION: Si c'est créole que vous connaissez, il y a un certain service de langues qui est gratis et disponible pour vous-même. Composez le numéro qui est au dos de votre carte d'identité. (TTY: 711).

ATTENTION: Si vous parlez français, les services d'assistance linguistique, gratuitement, sont à votre disposition. Appelez le numéro au dos de votre carte d'identité (TTY: 711).

UWAGA: Dla osób mówiących po polsku dostępna jest bezpłatna pomoc językowa. Zadzwoń pod numer podany na odwrocie karty ubezpieczenia zdrowotnego (TTY: 711).

ATENÇÃO: Se a sua língua é o português, temos atendimento gratuito para você no seu idioma. Ligue para o número no verso da sua identidade (TTY: 711).

ATTENZIONE: se parla italiano, per lei sono disponibili servizi di assistenza linguistica a titolo gratuito. Contatti il numero riportato sul retro della sua carta d'identità (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, steht Ihnen unsere fremdsprachliche Unterstützung kostenlos zur Verfügung. Rufen Sie dazu die auf der Rückseite Ihres Versicherungsausweises (TTY: 711) aufgeführte Nummer an.

注：日本語が母国語の方は言語アシスタンス・サービスを無料でご利用いただけます。ID カードの裏に明記されている番号に電話をおかけください (TTY: 711)。

توجه : اگر شما به زبان فارسی صحبت می کنید، خدمات کمک زبان، به صورت رایگان، در دسترس شماست. با شماره واقع در پشت کارت شناسایی خود (TTY: 711) تماس بگیرید.