

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (Generic)	ENTYVIO (vedolizumab)	
Status: CVS Caremark Criteria		MDC
Type: Initial Prior Authorization		Ref # 1155-A

FDA-APPROVED INDICATIONS¹

Adult Ulcerative Colitis

Entyvio 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 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 TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of moderately to severely active Crohn's disease? [If no, skip to question 3.]	Yes	No
2	Did the patient have an inadequate response, intolerance or contraindication to at least one conventional therapy option (e.g., corticosteroids, sulfasalazine, azathioprine, 6-mercaptopurine) OR a tumor necrosis factor (TNF) inhibitor for Crohn's disease (e.g., adalimumab)? [If yes, skip to question 5.] [If no, no further questions.]	Yes	No
3	Does the patient have a diagnosis of moderately to severely active ulcerative colitis? [If no, no further questions.]	Yes	No
4	Did the patient have an inadequate response, intolerance or contraindication to at least one conventional therapy option (e.g., oral aminosalicylates, corticosteroids, azathioprine, 6-mercaptopurine) OR a tumor necrosis factor (TNF) inhibitor for ulcerative colitis (e.g., adalimumab)? [If no, no further questions.]	Yes	No
5	Is the patient 18 years of age or older?	Yes	No

Guidelines for Approval			
Duration of Approval		12 Months	
Set 1: CD		Set 2: UC	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	3	1
2		4	
5		5	

Mapping Instructions			
	Yes		No
1	Go to 2	Go to 3	
2	Go to 5	Deny	
3	Go to 4	Deny	
4	Go to 5	Deny	
5	Approve, 12 months	Deny	

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2014.
2. Kornbluth A, Sachar DB, and the Practice Parameters Committee of the American College of Gastroenterology. Ulcerative Colitis Practice Guidelines in Adults. *Am J Gastroenterol.* 2010; 105:501–523. Available at <http://s3.gi.org/physicians/guidelines/UlcerativeColitis.pdf>. Accessed September 6, 2015.
3. Lichtenstein GR, Hanauer SB, Sandborn WJ, and the Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's disease in adults. *Am J Gastroenterol.* 2009. Available at <http://s3.gi.org/physicians/guidelines/CrohnsDiseaseinAdults2009.pdf>. Accessed September 6, 2015.
4. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol.* 2011;106(Suppl 1):S2-S25.

DOCUMENT HISTORY

Written: Specialty Clinical Development (DK) 06/2014
 Revised: DK 07/2014, 09/2014 (CMS); JP 08/2015 (CMS), IP 09/2015, 07/2016 (CMS); KF 08/2016; KF 02/2017 (trade, simplification), KF 07/2017 (CMS)
 Reviewed: CDPR/DNC 05/2014; SES 09/2014; MM 09/2015, 10/2015; ME 09/2016; SD 02/2017
 External Review: 06/2014, 11/2014, 10/2015, 11/2016