PRIOR AUTHORIZATION CRITERIA

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

FDA-APPROVED INDICATIONS[1]

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
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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