Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Entyvio (vedolizumab)

DRUG.00068

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Quantity Limit
Entyvio (vedolizumab)	1 vial per 56 days Initiation of therapy for both Crohn's Disease and Ulcerative Colitis: May allow up to 2 addition single use vials in the first 6 weeks (42 days) of treatment

APPROVAL CRITERIA

Requests for Entyvio (vedolizumab) may be approved if the following criteria are met:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologic includes – Humira (adalimumab), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)] unless the following is met:

   A. Individual has been receiving and is maintained on a stable dose of the Entyvio (vedolizumab); **OR**
   B. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Entyvio (vedolizumab) does; **OR**
   C. The preferred agent(s) are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
      1. Known hypersensitivity to any active or inactive component which is not also associated with Entyvio (vedolizumab); OR
      2. Individual's age; OR
      3. Pregnant or planning on becoming pregnant; OR
      4. Serious infections or concurrent sepsis; OR
   D. The preferred agent(s) do not have activity against a concomitant clinical condition and Entyvio (vedolizumab) does. Examples include but may not be limited to the following:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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1. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; OR
2. Concomitant Rheumatoid Arthritis: TNFi agents are preferred;

E. Individual has any of the following concomitant clinical conditions:
1. Demyelinating disease; **OR**
2. Heart failure with documented left ventricular dysfunction; **OR**
3. Malignancy [such as but not limited to, solid or hematologic cancers and excluding superficial skin cancers (such as basal and squamous cell)]; **OR**
4. Tuberculosis infection;

AND

II. Crohn's Disease when each of the following are met:
A. Individual is 6 years of age or older with moderately to severely active Crohn's disease; **AND**
B. Individual has failed to respond to, is intolerant of, or has a medical contraindication to either of the following:
1. A tumor necrosis factor (TNF) antagonist drug; **OR**
2. Conventional drug therapy, such as aminosalicylates/5-ASA products (for example, mesalamine, sulfasalazine), an immunomodulator (for example, 6-mercaptopurine, azathioprine or an immunosuppressive drug; **OR**
C. Individual has failed to respond to, is intolerant of or has demonstrated dependence on systemic corticosteroids; **AND**
D. Individual is using for one of the following:
1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical response or remission;

OR

III. Ulcerative colitis when each of the following are met:
A. Individual is 6 years of age or older with moderately to severely active ulcerative colitis; **AND**
B. Individual has failed to respond to, lost response to, is intolerant of, or has a medical contraindication to either of the following:
1. A TNF antagonist drug; **OR**
2. Conventional drug therapy such as aminosalicylates/5-ASA products (for example, mesalamine, sulfasalazine) an immunomodulator (for example, 6-mercaptopurine, azathioprine, or an immunosuppressive drug ; **OR**
C. Individual has failed to respond to, is intolerant of, or has demonstrated dependence on systemic corticosteroids; **AND**
D. Individual is using for one of the following:
1. To reduce signs or symptoms; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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2. To induce or maintain clinical remission or response and mucosal healing.

Entyvio (vedolizumab) may not be approved for an individual with any of the following:

I. In combination with TNF antagonist; **OR**
II. In combination with a non-TNF antagonist immunomodulator drug, such as natalizumab (Tysabri); **OR**
III. Active, serious infection or a history of recurrent infections; **OR**
IV. New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML).

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

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4. Entyvio [Product Information], Deerfield, IL. Takeda Pharmaceuticals America, Inc; May 20, 2014. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125476s000lbl.pdf. Accessed on December 29, 2016.
5. Kawalec P, Mikrut A, Łopuch S. Systematic review of the effectiveness of biological therapy for active moderate to severe ulcerative colitis. J Gastroenterol Hepatol. 2014; 29(6):1159-1170.
6. Kornbluth A, Sachar DB. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010; 105(3):501-523. Erratum in: Am J Gastroenterol. 2010; 105(3):500.
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