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

*FHK- Florida Healthy Kids

Entyvio (vedolizumab)

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

Medications	Quantity Limit
Entyvio (vedolizumab) 300mg/vial*	1 vial per 56 days (8 weeks)

*Initiation of therapy for both Crohn's Disease (CD) and Ulcerative Colitis (UC): May approve up to 2 (two) additional single-use vials (300mg/vial) in the first 6 weeks (42 days) of treatment

APPROVAL CRITERIA

Requests for Entyvio (vedolizumab) may be approved for the following:

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 (CD) when each of the following are met:
A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe CD; **AND**
B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalicilyc acid products, systemic corticosteroids, or immunosuppressants) or a tumor necrosis factor (TNF) antagonist;

OR

III. Ulcerative colitis (UC) when each of the following are met:
A. Individual is 6 years of age or older (Conrad 2016, Singh 2016) with moderate to severe UC; **AND**
B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as 5-Aminosalysilic acid products, systemic corticosteroids, or immunosuppressants) or a TNF antagonist.

Requests for Entyvio (vedolizumab) may **not** be approved for of the following:

I. In combination with T other biologic drugs (such as TNF antagonists or natalizumab); **OR**
II. Active, serious infection or a history of recurrent infections; **OR**
III. New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML).

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

Key References:

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5. American Gastroenterological Association. Identification, assessment and initial medical treatment of ulcerative colitis Clinical Care Pathway. Available at https://gastro.org/guidelines/ibd-and-bowel-disorders. Accessed on: September 14, 2018.
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7. Lichtenstein GR, Loftus EV, Isaacs KL et al. 2018 American College of Gastroenterology Guideline for the management of Crohn's disease in adults. *Am J Gastroenterol* 2018; 113:481–517.
8. Conrad MA, Stein RE, Maxwell EC, et al. Vedolizumab therapy in severe pediatric inflammatory bowel disease. Inflamm Bowel Dis. 2016; 22(10):2425-2431.
9. Singh N, Rabizadeh S, Jossen J, et al. Multi-center experience of vedolizumab effectiveness in pediatric inflammatory bowel disease. Inflamm Bowel Dis. 2016; 22(9):2121-2126.