Policy Title:	Entyvio (vedolizumab) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	09/18/2019, 12/18/19		
Revision Date:	09/18/2019		

Purpose: To support safe, effective and appropriate use of Entyvio (vedolizumab).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Entyvio (vedolizumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Entyvio (vedolizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient is greater than 18 years of age; AND
- Must be prescribed by, or in consultation with, a specialist in gastroenterology; AND
- Patient is free of any active, severe infections; AND
- Not on concurrent treatment with a biologic response modifier such as etanercept (Enbrel), adalimumab (Humira), certolizumab (Cimzia), golimumab (Simponi), ustekinumab (Stelara), infliximab (Remicade, Inflectra, or Renflexis), or natalizumab (Tysabri); AND
- Prescriber has assessed baseline disease severity utilizing an objective measure/tool; AND
- Dose does not exceed 300mg at weeks 0, 2, & 6 for loading doses and 300mg every 8 weeks for maintenance doses.

For Crohn's disease:

- Documented moderate to severe Crohn's disease; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with ONE of the following conventional oral agents: mesalamine, corticosteroids, 6-mercaptopurine, methotrexate, or azathioprine; AND

- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab (Humira), or infliximab (Inflectra, Renflexis, or Remicade).

For Ulcerative colitis:

- Documented moderate to severe Ulcerative colitis; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with ONE of the following conventional oral agents: mesalamine, corticosteroids, 6-mercaptopurine, methotrexate, or azathioprine; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab (Humira), or infliximab (Inflectra, Renflexis, or Remicade).

Continuation of therapy Criteria:

- Meet all initial approval criteria AND is tolerating treatment; AND
- Patient has been evaluated and screened for the presence of TB or other active infections; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis or other serious allergic reactions, severe infections, progressive multifocal leukoencephalopathy (PML), jaundice or other evidence of significant liver injury, etc.; AND
- For patients with Crohn's disease, disease response is indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight compared to IBW, hematocrit, presence of extraintestinal complications, and use of anti-diarrheal drugs; OR
- For patients with ulcerative colitis, disease response is indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, and/or endoscopic activity.

Dosage/Administration:

Indication	Dose	Maximum dosing (1 billable unit = 1 mg)
Ulcerative Colitis and Crohn's Disease	Loading dose: 300 mg , intravenously, at weeks 0, 2, & 6 Maintenance dose: 300 mg, intravenously, every 8 weeks thereafter	Loading Dose: 300 billable units at weeks 0, 2, & 6 Maintenance Dose: 300 billable units every 8 weeks

Coverage durations:

- Initial coverage: 14 weeks

- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of the billing code applicable for covered treatment options. The below table is provided for reference purposes and may not be all-inclusive. Requests received with code from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J3380	Injection, vedolizumab, 1 mg

References:

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3. Kornbluth A, Sachar DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010 Mar;105(3):501-23.
4. Dignass A, Lindsay JO, Sturm A, et al. Second European evidence-based consensus on the diagnosis and management of ulcerative colitis part 2: current management. J Crohns Colitis. 2012 Dec;6(10):991-1030.
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6. Gomollón F, Dignass A, Annese V, et al. EUROPEAN Evidence-based consensus on the diagnosis and management of Crohn's disease 2016: Part 1: Diagnosis and medical management. J Crohns Colitis. 2016 Sep 22. pii: jjw168.
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8. National Institute for Health and Care Excellence. NICE 2012. Crohn's Disease: Management. Published 10 October 2012. Clinical Guideline [CG152]. https://www.nice.org.uk/guidance/cg152/resources/crohns-disease-management-pdf35109627942085.
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