Policy Title:	Tysbari (natalizumab) (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	9/12/18, 12/13/2019		
Revision Date:	9/12/18, 12/13/2019		

Purpose: To support safe, effective and appropriate use of Tysbari (natalizumab) in the treatment of Multiple Sclerosis and Crohn's disease.

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

Policy Statement:

Tysbari (natalizumab) 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 Tysbari (natalizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria :

- Patient is at least 18 years of age; AND
- Patient has had anti-JCV antibody testing with ELISA prior to initiating treatment with natalizumab and annually thereafter; AND
- Cannot be used in combination with antineoplastic, immunosuppressant, or immunomodulating agents; AND
- Patient must not have a systemic medical condition resulting in significantly compromised immune system function; AND

Multiple Sclerosis (MS):

- Patient is diagnosed with a relapsing form of multiple sclerosis and documented by laboratory report (i.e. MRI); AND
- Member has failed, demonstrated intolerance, or is contraindicated to at least two drugs indicated for the treatment of relapsing MS; AND
- Must be prescribed by a neurologist; AND
- Used as monotherapy for the treatment of relapsing forms of MS; AND
- Dose does not exceed 300mg(300 billable units) every 28 days

Crohn's Disease:

- Patient is diagnosed with Crohn's disease by a gastroenterologist; AND
- Prescriber has assessed baseline disease severity utilizing an objective measure/tool; AND
- Patient has had failure, intolerance, or contraindication to at least two oral immunosuppressive therapy for at least 3 months, such as corticosteroids, methotrexate, azathioprine, and/or 6-mercaptopurine; AND
- Patient has had failure, intolerance, or contraindication to at least one TNF-Inhibitor therapy for at least 3 months; AND
- Patient is not taking in combination with another biologic drug or immunosuppressant (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate, etc) used for Crohn's disease.

Continuation of therapy criteria:

- Continuation of therapy criteria for MS:
  - Patient is tolerating treatment
  - Dose does not exceed 300mg (300 billable units) every 28 days
  - Patient has annual anti-JCV antibody testing with ELISA
  - Patient has experienced disease improvement or slowing of disease worsening (eg, no decline in Expanded Disability Status Score [EDSS] or MRI findings) since initiating therapy.
- Continuation of therapy criteria Crohn's disease:
  - Patient is tolerating treatment
  - Patient has annual anti-JCV antibody testing with ELISA
  - Dose does not exceed 300mg(300 billable units) every 28 days
  - For initial renewal only:
    - patient must show clinical response and remission of disease by 12 weeks
  - For all subsequent renewals:
    - Patient does not require additional steroid use that exceeds three months in a calendar year
    - Disease response as 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 extra intestinal complications, use of anti-diarrheal drugs, and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Crohn's Disease Activity Index (CDAI) score or the Harvey-Bradshaw Index score.]

Coverage durations:

- Initial coverage criteria = 3 months for Crohn's disease and 6 months for MS
- Continuation of therapy = 6 months

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

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = *1* mg)
All Indications	300 mg intravenously over one hour every four weeks	300 billable units every 28 days

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 billing codes applicable to covered treatment options for multiple sclerosis. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria are provided in the procedure section.

Codes:

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2323	Injection, natalizumab, 1mg

References:

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10. Tysabri prescribing information. South San Francisco, CA: Elan Pharmaceuticals, Inc.; 2018 July.