Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 09/01/2019**
Policy Number: PHW.PDL.043.01	**Effective Date: 01/01/2020** **Revision Date: 09/01/2019**
Policy Name: Natalizumab (Tysabri)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy created.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Natalizumab (Tysabri)

Reference Number: PHW.PDL.043.01
Effective Date: 01/01/2020
Last Review Date: 09/01/2019

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Natalizumab (Tysabri) is **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Tysabri

A. Prescriptions That Require Prior Authorization

All prescriptions for Tysabri must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Tysabri, determination of whether the requested prescription is medically necessary will take into account whether:

1. The recipient:

a. Has a diagnosis of a relapsing form of Multiple Sclerosis (MS)

AND

b. Is 18 years of age or older

AND

c. Is not receiving chronic immunosuppressant or immunomodulatory therapy

AND

d. Had a Magnetic Resonance Imaging (MRI) scan prior to initiating Tysabri therapy to help differentiate MS symptoms from progressive multifocal leukoencephalopathy (PML)

AND

e. Had baseline testing for anti-JC virus antibodies; if baseline testing for anti-JC virus was negative, had repeat testing for anti-JC virus antibodies

AND

f. **For requests for prior authorization of RENEWALS of prescriptions for Tysabri that were previously approved**, whether the recipient's Multiple Sclerosis disease course improved or stabilized as documented by the prescriber

OR

2. The recipient:

a. Has a diagnosis of moderately to severely active Crohn's Disease with inflammation

AND

b. Is 18 years of age or older

AND

c. Is not receiving chronic immunosuppressant or immunomodulatory therapy

AND

d. Has a documented history of therapeutic failure of a trial (see chart below for trial timeframes) of, or contraindication or intolerance of the following conventional therapies:

i. Aminosalicylates **AND**
ii. Immunomodulators

Aminosalicylates	**Trial Timeframe**
Mesalamine	3 months
Sulfazalazine	3 months
Immunomodulators	**Trial Timeframe**
Azathioprine	3 months
Methotrexate	3 months
6-Mercaptopurine	3 months

AND

e. Has a documented history of:

i. Therapeutic failure of a trial (see chart below for trial timeframes) of preferred Inhibitors of TNF- α that are in the Cytokine and CAM Antagonist class of drugs on the Preferred Drug List

OR

ii. Contraindication or intolerance to preferred Inhibitors of TNF- α that are in the Cytokine and CAM Antagonist class of drugs on the Preferred Drug List

TNF- α Inhibitor	**Trial Timeframe**
Cimzia	6 weeks
Humira	3 months
Remicade	10 weeks

AND

f. Had baseline testing for anti-JC virus antibodies

3. **For a RENEWAL of a request for prior authorization that was previously approved**, whether:

a. The recipient has experienced therapeutic benefit by 3 months of therapy induction

OR

b. The recipient can discontinue concomitant corticosteroid use within 6 months of starting therapy

AND

c. If baseline testing for anti-JC virus was negative, had repeat testing for anti-JC virus antibodies

NOTE: Requests for renewal of the prescription will not be approved if the recipient requires additional steroid use that exceeds 3 months in a calendar year to control their Crohn's disease.

OR

4. Does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for Tysabri. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the recipient.

D. **Approval Duration:**

PA Health & Wellness will limit authorization of Tysabri as follows:

1. For a diagnosis of moderately to severely active Crohn's Disease with inflammation:

   a. Initial requests will be limited to:

      i. Three (3) months if the recipient is not taking chronic oral corticosteroids while starting Tysabri

      OR

      ii. Six (6) months if the recipient is on chronic oral corticosteroids while starting Tysabri to allow tapering of the corticosteroids

   b. Requests for renewals of prescriptions that were previously approved will be approved for a period of 12 months.

2. For a diagnosis of relapsing Multiple Sclerosis (MS):

   a. Initial requests will be limited to six (6) months

   b. Requests for renewals of prescriptions that were previously approved will be approved for a period of 12 months

E. References

1. Tysabri package insert. Biogen Idec Inc, 2012
2. Goodin, DS et.al. "Assessment: the use of natalizumab (Tysabri) for the treatment of multiple sclerosis (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology" *Neurology* 2008;71;766-773.
3. Goodin DS, et.al. ".Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines" *Neurology* 2002 Jan 22;58(2):169-78.
4. Farrell, RJ et.al. "Overview of the management of Crohn's disease in Adults" UpToDate ONLINE. Updated March 11, 2010. Accessed August 19, 2010.
5. Olek, MJ. "Treatment of relapsing-remitting multiple sclerosis in adults" UpToDate ONLINE. Updated June 8, 2010. Accessed August 19, 2010.
6. Macdermott R.P. "Immunomodulator therapy in Crohn's disease" UpToDate ONLINE. Updated June 2, 2010. Accessed August 19, 2010.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020