

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Tysabri (natalizumab)
BILLING CODE	J2323 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product for Crohn's Disease includes Cimzia QUANTITY LIMIT— 300 units/mg per 28 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Tysabri (natalizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### CROHN'S DISEASE (CD)

For **initial** authorization:

1. Medication is prescribed by a gastroenterologist; AND
2. Member must be at least 18 years or older moderate to severe CD; AND
3. Member has documentation in chart notes that member was tested for John Cunningham virus (JCV) with ELISA prior to initiating treatment; AND
4. Medication is **not** being used in combination with immunosuppressant's or TNF-alpha inhibitors; AND
5. Member has documented inadequate response or contraindication to trial of at least **two** different therapies such as:
  - a) Corticosteroids (e.g., budesonide (Entocort), prednisone));
  - b) Methotrexate (e.g., Rheumatrex);
  - c) Immunosuppressants (e.g., 6-mercaptopurine (Purinethol), Azathioprine (Imuran) or cyclosporine (Neoral, Sandimmune, Gengraf)).
6. **Dosage allowed:** 300 mg intravenous infusion over one hour every 4 weeks.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS), SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
3. Member has documentation in chart notes that member was tested for John Cunningham virus (JCV) with ELISA prior to initiating treatment; AND
4. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug). Treatment failure requires at least 3 months of therapy without an adequate response.
5. **Dosage allowed:** 300 mg intravenous infusion over one hour every 4 weeks.

***If member meets all the requirements listed above, the medication will be approved for 12 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Tysabri (natalizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Clinically Isolated Syndrome (CIS) in Multiple Sclerosis
- Primary Progressive Multiple Sclerosis

DATE	ACTION/DESCRIPTION
05/10/2017	New policy for Tysabri created. Policy SRx-0041 archived. For diagnosis of CD: trial of Humira required. For RRMS and SPMS diagnoses trial of two formulary agents required. List of diagnoses considered not medically necessary was added.
12/06/2017	Age coverage expanded.
02/26/2019	Humira trial removed from criteria for CD.

### References:

1. Tysabri [package insert]. Cambridge, MA; Biogen, Inc.: December, 2016.
2. American Gastroenterological Association. Identification, assessment and initial medical treatment in Crohn's disease. AGA institute. 2014. <http://www.gastro.org/IBDcarepathway>. Accessed April 20, 2017.
3. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Use of Thiopurines, Methotrexate, and Anti-TNF- $\alpha$  Biologic Drugs for the Induction and Maintenance of Remission in Inflammatory Crohn's Disease. *Gastroenterology* 2013; 145:1459-1463.
4. Goodin DS, Frohman EM, Garmany GP Jr, 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;58(2):169-78.

Effective date: 04/01/2019

Revised date: 02/26/2019