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PHARMACY POLICY STATEMENT
Kentucky 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 **NOT** MEDICALLY NECESSARY	Click Here

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.

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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 30 days 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-a 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.

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Revised date: 02/26/2019