# MEDICAL POLICY STATEMENT

| Original Effective Date | Next Annual Review Date | Last Review / Revision Date |
|---|---|---|
| 10/15/2013 | 10/15/2015 | 10/15/2014 |

| Policy Name | Policy Number |
|---|---|
| **Tysabri® (natalizumab) for Treatment of Crohn's Disease** | **SRx-0031** |

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

## A. SUBJECT

Tysabri®, natalizumab: Treatment of Crohn's Disease

## B. BACKGROUND

The CareSource Medication Policies are policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan and after consultation with the treating provider.

The intent of the **Tysabri® (natalizumab)** (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

## C. DEFINITIONS

N/A

## D. POLICY

**Crohn's Disease**

Tysabri is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α.

Due to the risk of Progressive Multifocal Leukoencephalopathy (PML) with natalizumab therapy, CareSource follows the recommendations that natalizumab be reserved for use in select patients

with Crohn's disease who have failed other therapies either through continued disease activity or medication intolerance.

CareSource will approve the use of **Tysabri® (natalizumab)**, and consider its use as medically necessary when ALL of the following criteria have been met:

- Natalizumab is prescribed by, or in consultation with, a gastroenterologist for the indication of Crohn's disease
- Failure of conventional therapy such as:
  - 5-ASA products (e.g. mesalamine (Asacol, Pentasa, Asacol HD, Delzicol, Apriso), sulfasalazine (Azulfidine))
  - Methotrexate (e.g. Rheumatrex)
  - Systemic corticosteroids (e.g. budesonide (Entocort), prednisone)
  - Immunosuppressants (e.g. 6-mercaptopurine (Purinethol))
  - Intolerant of or no longer responsive to infliximab
  - Azathioprine (Imuran) or cyclosporine (Neoral, Sandimmune, Gengraf)
    **OR**
  - Unable to tolerate or has a medical contraindication of conventional therapies
- Infliximab (Remicade®) is not effective after at least an initial induction period (5mg/kg on weeks 0, 2 and 6), except if not tolerated due to documented clinical side effects
- Adalimumab (Humira®) is not effective after at least an initial 3-dose induction period (Day1=160mg; Day 15=80mg; Day 29=40mg), except if not tolerated due to documented clinical side effects

For the use of Tysabri in the treatment of MS, refer to CareSource's Multiple Sclerosis policy. **ALL** other uses of Tysabri are considered experimental/investigational and therefore, will follow CareSource's off-label policy.

**NOTE:** Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office or hospital admission notes.

**Refer to the product package insert for doing, administration and safety guidelines.**

**For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):**

**If there is no NCD or LCD present, reference the CareSource Policy for coverage.**

**CONDITIONS OF COVERAGE**
**Place of Service** Outpatient
This medication is an infusion medication that must meet TOUCH prescribing program requirements for infusion.

**Note**: Tysabri is available only through a restricted REMS program called the TOUCH prescribing program because of the risk of PML. Prescriber and patients must be enrolled in the TOUCH prescribing program and comply with the guidelines of the program. Pharmacies and infusion centers must be specially certified through the TOUCH program to dispense or infuse TYSABRI.

**Note: Pharmacies may only dispense Tysabri to authorized infusion sites.**

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**CPT**

**AUTHORIZATION PERIOD**
Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment. ALL authorizations are subject to continued eligibility. Subsequent authorization shall be reviewed at least every six months to confirm that current medical necessity criteria are met and that the medication is effective.

## E. REVIEW/REVISION HISTORY

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| Date Issued: | 10/15/2013 |
| Date Reviewed: | 10/15/2013, 10/15/2014 |
| Date Revised: | 10/15/2014 – Updated references, added information about REMS program, indication, deleted PA criteria about concurrent use with DMARD. |

## F. REFERENCES


1. Tysabri [package insert]. Cambridge, MA: Biogen Idec Inc.; December 2013.
2. Lichtenstein GR, Hanauer SB, Sandborn WJ. Practice Parameters Committee of American College of Gastroenterology. Management of Crohn's disease in adults. *Am J Gastroenterol*. 2009 Feb;104(2):465-83.
3. Terdiman JP, Gruss CB, Heidelbaugh JJ, Sultan S, Falck-Ytter YT; AGA Institute Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology.* 2013 Dec;145(6):1459-63.
4. Miilimans Cinical Guidelines 18th ed.


"This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC."

**The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**