Tysabri (natalizumab)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Tysabri drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For members diagnosed with Multiple Sclerosis*, Betaseron, Copaxone, generic dimethyl fumarate, generic fingolimod, glatiramer acetate, Glatopa, Kesimpta, Mayzent, Ponvory, Rebif, generic teriflunomide, Vumerity, and Zeposia** are the preferred products. The criteria will require the use of the health plan's preferred products for multiple sclerosis (Betaseron, Copaxone, generic dimethyl fumarate, generic fingolimod, glatiramer acetate, Glatopa, Kesimpta, Mayzent, Ponvory, Rebif, generic teriflunomide, Vumerity, and Zeposia**) before the use of targeted product (brand Aubagio, Bafiertam, Extavia, brand Gilenya, Tascenso ODT, and brand Tecfidera) unless there are clinical circumstances that exclude the use of the preferred products. The program also considers Ocrevus and Tysabri preferred products. The criteria will require the use of the health plan's preferred products for multiple sclerosis, Ocrevus and Tysabri, before the use of a targeted product, Briumvi or Lemtrada. Avonex, Mavenclad, and Plegridy, are excluded from the preferred multiple sclerosis product requirements.

*For policies regarding aforementioned multiple sclerosis agents, please refer to the Multiple Sclerosis policy.
**For policy regarding Zeposia, please refer to the Zeposia policy.

FDA-Approved Indications

1. Tysabri (natalizumab) is indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor alpha (TNF-α). In CD, Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.
2. Tysabri (natalizumab) is indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
B. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties

Medication must be prescribed by or in consultation with a neurologist, gastroenterologist, or other provider specializing in the management of Crohn's disease or multiple sclerosis, when applicable.

Criteria for Initial Approval

A. Crohn's Disease

Tysabri (natalizumab) may be considered **medically necessary** for members when ALL of the following criteria have been met:

a. Member has been diagnosed with moderately to severely active Crohn's disease (CD).
b. Member has been tested for anti-JCV antibodies.
c. Member will not use Tysabri concomitantly with other disease modifying multiple sclerosis agents. (Note: Ampyra (dalfampridine) and Nuedexta (dextromethorphan/quinidine) are not disease modifying agents.)
d. Member will not use Tysabri concomitantly with immunosuppressants or TNF-inhibitors (e.g., adalimumab, infliximab).

Approval will be for **12 months.**

B. Multiple Sclerosis

Tysabri (natalizumab) may be considered **medically necessary** for members when ALL of the following criteria have been met:

a. Member has been diagnosed with a relapsing form of MS (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).
b. Member has been tested for anti-JCV antibodies.
c. Member will not use Tysabri concomitantly with other disease modifying multiple sclerosis agents. (Note: Ampyra (dalfampridine) and Nuedexta (dextromethorphan/quinidine) are not disease modifying agents.)
d. Member will not use Tysabri concomitantly with immunosuppressants or TNF-inhibitors (e.g., adalimumab, infliximab).

Approval will be for **12 months.**

Tysabri (natalizumab) may be considered **medically necessary** for members when ALL of the following criteria have been met:

a. Member has been diagnosed with clinically isolated syndrome of multiple sclerosis.
b. Member has been tested for anti-JCV antibodies.
c. Member will not use Tysabri concomitantly with other disease modifying multiple sclerosis agents. (Note: Ampyra (dalfampridine) and Nuedexta (dextromethorphan/quinidine) are not disease modifying agents.)

d. Member will not use Tysabri concomitantly with immunosuppressants or TNF-inhibitors (e.g., adalimumab, infliximab).

Approval will be for **12 months**

Tysabri (natalizumab) is considered **not medically necessary** for patients who do not meet the criteria set forth above.

Continuation of Therapy

The continuation of Tysabri (natalizumab) may be considered **medically necessary** for members when any of the following are met:

1. Member is using Tysabri (natalizumab) for moderately to severely active Crohn's disease and has achieved or maintained remission and chart notes or medical record documentation supporting positive clinical response to therapy or remission has been submitted.

2. Member is using Tysabri (natalizumab) for moderately to severely active Crohn's disease and has achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline (chart notes or medical record documentation supporting positive clinical response to therapy or remission are required to be submitted):
   a. Abdominal pain or tenderness
   b. Diarrhea
   c. Body weight
   d. Abdominal mass
   e. Hematocrit
   f. Endoscopic appearance of the mucosa
   g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

3. Member is using Tysabri (natalizumab) for the treatment of relapsing forms of multiple sclerosis or clinically isolated syndrome of multiple sclerosis and has achieved or maintained a positive clinical response as evidenced by experiencing disease stability or improvement (chart notes or medical record documentation supporting positive clinical response to therapy or remission are required to be submitted).

   Approval will be for **12 months**

Tysabri (natalizumab) is considered **not medically necessary** for patients who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

One 300 mg/ 15 mL vial will be allowed every 28 days.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2323 – Injection, Natalizumab, 1 mg

REFERENCES

- Tysabri [package insert]. Cambridge, MA: Biogen Inc.; June 2022.
- The Multiple Sclerosis Coalition. *The use of disease-modifying therapies in multiple sclerosis: principles and current evidence.* http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed October 01, 2019.
- Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. Am J Gastroenterol. 2011;106(Suppl 1):S2-S25.
- Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.
- Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroentrol. 2019;114:384-413.
- Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology 2020; 158:1450-1461.
- Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology 2021; 160: 2496- 2508.

POLICY HISTORY

Policy #: 05.04.91
Original Effective Date: August 2008
Reviewed: June 2023
Revised: January 2023
Current Effective Date: April 10, 2023