

Tysabri® (natalizumab) injection

When requesting Tysabri® (natalizumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved Indications

- Multiple Sclerosis
- Crohn's disease

Coverage Guidelines

Multiple Sclerosis (MS)

The individual must meet **all** of the following criteria for **initial authorization**:

- 1) Has a relapsing form of multiple sclerosis (examples include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive MS); AND
- 2) Is 18 years of age or older: AND
- 3) Tysabri is prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis (MS) and/or neurologist; AND
- 4) The patient meets ONE of the following (a or b):
 - a) Has experienced inadequate efficacy or significant intolerance to one disease-modifying agent used for MS (e.g., Avonex® (interferon beta-1a injection [intramuscular]), Rebif® (interferon beta-1a injection [subcutaneous]), Betaseron®/Extavia® (interferon beta-1b injection), glatiramer acetate injection (Copaxone®/Glatopa®, generic), Plegridy® (peginterferon beta-1a injection), Gilenya® (fingolimod capsules), Aubagio® (teriflunomide tablets), Mavenclad® (cladribine tablets), Mayzent® (siponimod tablets), Vumerity® (diroximel fumarate delayed-release capsules), Ocrevus® (ocrelizumab injection for intravenous use), Bafiertam™ (monomethyl fumarate delayed-release capsules), dimethyl fumarate delayed-release capsules (Tecfidera®, generic), Zeposia® (ozanimod capsules), Kesimpta® (ofatumumab injection for subcutaneous use), and Lemtrada® (alemtuzumab injection for intravenous use); OR
 - b) Has highly-active or aggressive multiple sclerosis defined as one of the following: [(1), (2), (3), or (4)]:
 - (1) Rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination); OR
 - (2) Disabling relapse with suboptimal response to systemic corticosteroids; OR
 - (3) Magnetic resonance imaging [MRI] findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium-enhancing lesions); OR
 - (4) Manifestations of multiple sclerosis-related cognitive impairment.

The individual must meet **all** of the following criteria for **reauthorization**:

- 1) Has a relapsing form of multiple sclerosis (examples include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive MS); AND
- 2) Is 18 years of age or older; AND
- 3) Prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis (MS) and/or neurologist.

Crohn's disease (CD)

The individual must meet **all** of the following criteria for **initial authorization**:

- 1) Has moderately to severely active Crohn's disease; AND
- 2) Is 18 years of age or older; AND
- 3) Tysabri is prescribed by or in consultation with a gastroenterologist; AND
- 4) Has tried at least two biologics for Crohn's disease (e.g., an adalimumab product, Cimzia (certolizumab pegol for SC injection), an infliximab product, Entyvio (vedolizumab injection for IV use), or Stelara (ustekinumab for SC injection or for IV infusion).

The individual must meet **all** of the following criteria for **reauthorization**:

- 1) Has had a response to Tysabri (e.g., reduced number of liquid/soft stools, reduced abdominal pain, less use of antidiarrheal agents); AND
- 2) Is 18 years of age or older; AND
- 3) Tysabri is prescribed by or in consultation with a gastroenterologist.

Approval duration

MS (initial and reauthorization): 1 year

CD initial: 3 months; reauthorization: 1 year

Dosing Recommendations

Approve up to 300 mg given by intravenous infusion administered no more frequently than once every 4 weeks.

References

1. Tysabri® injection for intravenous use [prescribing information]. Cambridge, MA: Biogen; June 2020.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed on November 6, 2020.
3. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
4. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.
5. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018;90:777-788.
6. Torres J, Mehandru S, Solombel JF, Peyrin-Biroulet L. Crohn's disease. *Lancet*. 2017;389(10080):1741-1755.
7. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113:481-517.
8. Gordon FH, Hamilton MI, Donoghue S, et al. A pilot study of treatment of active ulcerative colitis with natalizumab, a humanized monoclonal antibody to alpha-4 integrin. *Aliment Pharmacol Ther*. 2002;16:699-705.