

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

For All Members (initial and reauthorization):

- 1) Is 18 years of age or older

Initial authorization **Multiple Sclerosis (MS):**

The individual must meet **all** of the following criteria for approval (1, 2, and 3):

- 1) Has a relapsing form of multiple sclerosis (MS)
- 2) Prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis (MS) and/or neurologist
- 3) The patient meets ONE of the following (a or b)
 - a) Inadequate response or is unable to tolerate ONE disease modifying agent used for MS (e.g., Avonex [interferon beta-1a for intramuscular {IM} injection], Rebif [interferon beta-1a for subcutaneous {SC} injection], Betaseron [interferon beta-1b for SC injection], Extavia [interferon beta-1b for SC injection], Copaxone [glatiramer acetate injection for SC use], Glatopa [glatiramer acetate injection for SC use], Plegridy [peginterferon beta-1a SC injection], Gilenya [fingolimod capsules], Aubagio [teriflunomide tablets], Tecfidera [dimethyl fumarate delayed-release capsules], Mavenclad [cladribine tablets], Mayzent [siponimod tablets], Vumerity [diroximel fumarate delayed-release capsule], Lemtrada [alemtuzumab injection for intravenous use], or Ocrevus [ocrelizumab injection for IV use]); OR
 - b) According to the prescribing physician the patient has highly-active or aggressive multiple sclerosis by meeting one of the following [(1), (2), (3), or (4)]:
 - (1) The patient has demonstrated 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(s) with suboptimal response to systemic corticosteroids
 - (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)
 - (4) Manifestations of multiple sclerosis-related cognitive impairment

Reauthorization MS:

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

- 1) Has a relapsing form of multiple sclerosis (MS)

- 2) Prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis (MS) and/or neurologist

Initial authorization for **Crohn's disease (CD)**:

The individual must meet all of the following criteria for approval (1, 2, and 3):

- 1) Patient has moderately to severely active Crohn's disease; AND
- 2) Tysabri is prescribed by or in consultation with a gastroenterologist; AND
- 3) Patient has tried at least two biologics for Crohn's disease: Humira (adalimumab for subcutaneous [SC] injection), 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)

Reauthorization of CD:

- 1) The patient has had a response (e.g., reduced number of liquid/soft stools, reduced abdominal pain, less use of antidiarrheal agents) to Tysabri; AND
- 2) 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

Multiple Sclerosis and Crohn's Disease- 300mg every 4 weeks

References

1. Tysabri® injection for intravenous use [prescribing information]. Cambridge, MA: Biogen; August 2019.
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 7, 2019.
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.