

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, 3, 4, and 5):

- 1) Has a relapsing form of multiple sclerosis (MS) [relapsing forms of MS are relapsing-remitting MS [RRMS], secondary-progressive [SPMS], and progressive-relapsing MS [PRMS]
- 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], 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
- 4) Will not be used with other disease modifying agents or with an immunosuppressant
- 5) Is not immune compromised (i.e HIV, leukemia, lymphoma, organ transplant, or etc)

Reauthorization MS:

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

- 1) Has a relapsing form of multiple sclerosis (MS) [relapsing forms of MS are relapsing-remitting MS [RRMS], secondary-progressive [SPMS], and progressive-relapsing MS [PRMS]
- 2) Prescribed by or in consultation with a physician who specializes in the treatment of multiple sclerosis (MS) and/or neurologist
- 3) Will not be used with other disease modifying agents or with an immunosuppressant.
- 4) Is not immune compromised (i.e. HIV, leukemia, Lymphoma, organ transplant, or etc.)

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 with evidence of inflammation, that is, has an elevated C-reactive protein; AND
- 2) Tysabri is prescribed by or in consultation with a gastroenterologist; AND
- 3) Patient has tried at least two of the following agents for Crohn's disease: Humira (adalimumab for subcutaneous [SC] injection), Cimzia (certolizumab pegol for SC injection), an infliximab product (for example, Remicade [infliximab for IV infusion], Inflectra [infliximab-dyyb IV infusion]), Entyvio™ (vedolizumab injection for IV use), or Stelara® (ustekinumab for SC injection or for IV infusion) for at least 2 months each and had an inadequate response or was intolerant to these agents; AND
- 4) Will not be used with an immunosuppressant agent; AND
- 5) Is not immune compromised (i.e. HIV, leukemia, lymphoma, organ transplant, or etc.)

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, as determined by the prescribing physician; AND
- 2) Tysabri is prescribed by or in consultation with a gastroenterologist; AND
- 3) Will not be used with an immunosuppressant agent; AND
- 4) Is not immune compromised (i.e. HIV, leukemia, lymphoma, organ transplant, or etc)

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

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