

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 indications¹

- Multiple Sclerosis
- Crohn's disease

Approved Off-label Compendial uses

- None

Coverage Guidelines

For All Members:

- Does not have anti-JCV antibodies
- Is 18 years of age or older

For Crohn's disease

Initial authorization:

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

- Has moderately- to severely-active Crohn's disease with evidence of inflammation¹
- Had an inadequate response or intolerance to at least 2 conventional therapies and at least one TNF-inhibitor¹
 - Conventional therapies include aminosalicylates (e.g., mesalamine, sulfasalazine), corticosteroids and immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate)
 - TNF-inhibitors include: infliximab (Remicade®), infliximab-dyyb (Inflectra®), adalimumab (Humira®), certolizumab pegol (Cimzia®)^{3,4}
- Tysabri® (natalizumab) is not used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) or TNF-inhibitors¹

Approval duration: 12 weeks

Reauthorization:

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

- Has experienced therapeutic benefit by 12 weeks of induction therapy¹
- Has been tapered off chronic oral corticosteroids within 6 months of starting Tysabri® (natalizumab)¹
- Has not required additional steroid use that exceeds 3 months to control Crohn's disease¹

- Does not have jaundice or other evidence of significant liver injury
- Has not developed an opportunistic infection

For multiple sclerosis

Initial authorization:

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

- Has a relapsing form of multiple sclerosis¹
- Use Tysabri® (natalizumab) as monotherapy¹

Reauthorization:

The individual must be meet **both** of the following for approval:

- Does not have jaundice or other evidence of significant liver injury
- Has not developed an opportunistic infection

Additional Information for Prescribers¹

*(**Black Box Warning**) Because of the risk of progressive multifocal leukoencephalopathy (PML), Tysabri® (natalizumab) is available only under a restricted distribution program, the TOUCH® prescribing program.

- Risk factors for development of PML include duration of therapy, prior use of immunosuppressants, and presence of anti-JCV antibodies. These factors should be considered in the context of expected benefit when initiating and continuing treatment with Tysabri® (natalizumab). Tysabri® (natalizumab) dosing should be withheld immediately at the first sign or symptom suggestive of PML.
- Testing for anti-natalizumab antibodies should be considered for patients recommencing therapy following a dose interruption. Patients who receive Tysabri® (natalizumab) for a short exposure (1 to 2 infusions) followed by an extended period without treatment are at higher risk of developing anti-natalizumab antibodies and/or hypersensitivity reactions on re-exposure, compared to patients who received regularly scheduled treatment.
- Tysabri® (natalizumab) should be discontinued in an individual with jaundice or other evidence of significant liver disease. The individuals should be monitored for signs or symptoms of liver injury, including elevations in liver transaminases (AST, ALT) and total bilirubin
- Tysabri® may increase the risk of certain infections. The individual should be monitored for development of infections
- Life-threatening and fatal cases of herpes encephalitis and meningitis have occurred while on Tysabri® (natalizumab). Discontinue Tysabri® (natalizumab) if this occurs and treat appropriately

References

1. Tysabri® prescribing information. Cambridge, MA: Biogen Idec Inc.: Revised May 2016. Accessed January 18, 2017. https://www.tysabri.com/content/dam/commercial/multiple-sclerosis/tysabri/pat/en_us/pdfs/tysabri_prescribing_information.pdf
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed January 18, 2017. <http://www.micromedexsolutions.com>
3. Lichtenstein GR, Hanauer SB, Sandborn WJ, et al. ACG Practice Guidelines. Management of Crohn's disease in adults. Am J Gastroenterol. 2009 Feb; 104(2):465-483. Accessed January 19, 2017. <http://www.nature.com/ajg/journal/v104/n2/full/ajg2008168a.html>
4. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. 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):1459-1463. Accessed November 12, 2015. [http://www.gastrojournal.org/article/S0016-5085\(13\)01521-7/fulltext](http://www.gastrojournal.org/article/S0016-5085(13)01521-7/fulltext)