

Tysabri (natalizumab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Multiple sclerosis (MS) and Crohn's disease are both chronic inflammatory diseases, although they affect different areas of the body. MS is a neurological condition that affects the central nervous system (brain and spinal cord), whereas Crohn's disease is a type of inflammatory bowel disease that primarily affects the digestive tract. In both MS and Crohn's disease, the body's immune system mistakenly attacks healthy cells, leading to inflammation and damage. The symptoms and severity of these diseases can vary widely among individuals.

Treatment for both conditions often involves medications to reduce inflammation and modulate the immune response. Tysabri (natalizumab) is one such treatment option. It is a monoclonal antibody that works by inhibiting the movement of immune cells into the brain and spinal cord in MS, and into the digestive tract in Crohn's disease, thereby reducing inflammation and damage.

Tysabri (natalizumab) is indicated for the treatment of relapsing forms of MS and for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to, or are unable to tolerate, conventional therapies and inhibitors of TNF-alpha.

NOTE: Access to Tysabri is managed through a Risk Evaluation and Mitigation Strategy (REMS) program known as the TOUCH Prescribing Program.

- In order to prescribe or dispense Tysabri, healthcare providers and pharmacies need to be certified with the Tysabri Outreach Unified Commitment to Health (TOUCH) Prescribing Program.
- Members who are prescribed Tysabri must be enrolled in the TOUCH Prescribing Program as well. They can do so by calling 800-456-2255. Depending on their condition, they will be enrolled either in the MS-TOUCH program for multiple sclerosis or the CD-TOUCH program for Crohn's disease.

Definitions

"Crohn's Disease" is a type of inflammatory bowel disease that can affect any part of the digestive tract, from the mouth to the anus. It causes symptoms such as diarrhea, abdominal pain, weight loss, and fatigue.

"Monoclonal Antibody" is a type of protein made in the lab that can bind to specific substances in the body. Monoclonal antibodies are used to treat many diseases, including some types of cancer and autoimmune disorders.

"Multiple Sclerosis (MS)" refers to a chronic disease that affects the central nervous system (brain and spinal cord), causing symptoms such as fatigue, difficulty walking, numbness or tingling, muscle weakness and spasms, poor balance and coordination, and problems with thinking and memory.

"TNF-alpha inhibitors" are a type of medication that works by blocking the protein, tumor necrosis factor-alpha (TNF-alpha), which plays a role in causing inflammation in the body. These medications are used to treat a variety of conditions, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and inflammatory bowel diseases like Crohn's disease.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Tysabri (natalizumab)** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

1. The member is 18 years of age or older; **AND**
2. The member does **NOT** have **ANY** of the following:
 - a. Current or history of progressive multifocal leukoencephalopathy (PML); **or**
 - b. Documentation indicating that the member will use Tysabri (natalizumab) in combination with any of the following:
 - i. Antineoplastic therapy (e.g., cyclophosphamide, doxorubicin, vincristine); **or**
 - ii. Immunosuppressants (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, 6-MP); **or**
 - iii. Immunomodulatory therapy (e.g., ocrelizumab, ofatumumab, TNF- α inhibitors - such as adalimumab, infliximab, etanercept, golimumab, certolizumab pegol);
AND
3. Tysabri (natalizumab) will be dosed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature; **AND**
4. The member meets the medical necessity criteria for the applicable indication listed below:

Crohn's Disease (CD)

5. Prescribed by or in consultation with a gastroenterologist; **AND**
6. The member has a documented diagnosis of moderately to severely active CD with evidence of inflammation (e.g., elevated C-reactive protein, fecal calprotectin, erythrocyte sedimentation rate, and/or imaging findings such as mucosal ulcerations or strictures); **AND**
7. The member is unable to use, or has tried and failed **BOTH** of the following:
 - a. at least **ONE** conventional CD therapy (e.g., corticosteroids, immunomodulators); **and**
 - b. at least **TWO** TNF inhibitors (e.g., adalimumab, certolizumab, infliximab).

Multiple Sclerosis (MS)

5. Prescribed by or in consultation with a neurologist; **AND**
6. The member has **ONE** of the following forms of multiple sclerosis:
 - a. Relapsing-remitting (RRMS); **or**
 - b. Active secondary progressive (SPMS); **or**
 - c. Clinically isolated syndrome (CIS); **AND**
7. Baseline MRI scan will be obtained prior to initiating therapy; **AND**
8. Tysabri will be used as monotherapy (i.e., will **NOT** be used concurrently with disease modifying therapies).

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if the member has recent (within the last 3 months) clinical chart documentation demonstrating **ALL** of the following criteria:

1. The member still meets the applicable **Initial Authorization** criteria; **AND**
2. Chart documentation shows **ONE** of the following:
 - a. For Multiple Sclerosis:
 - i. The member has shown a clinical improvement (e.g., reduction in neurologic disability and/or the frequency of clinical relapses) in symptoms since starting the requested medication; **or**
 - ii. The member has experienced disease stability since starting the requested medication; **or**
 - b. For Crohn's Disease:
 - i. The member has shown a clinical improvement (e.g., reduction in Crohn's disease symptoms) since starting the requested medication; **or**
 - ii. The member has experienced disease stability since starting the requested medication.

Experimental or Investigational / Not Medically Necessary

Tysabri (natalizumab) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- for use in pediatric patients (under 18 years of age) for any indication. The safety and efficacy of natalizumab in pediatric patients have not been established.
- other autoimmune diseases, such as rheumatoid arthritis, lupus, or psoriasis.

Applicable Billing Codes (HCPCS/CPT Codes)

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| Service(s) name | |
| CPT/HCPCS Codes considered medically necessary if criteria are met: | |
| <i>Code</i> | <i>Description</i> |
| 96365 | Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour |

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| J2323 | Injection, natalizumab, 1 mg |
| Q5134 | Injection, natalizumab-sztn (tyruko), biosimilar, 1 mg |
| ICD-10 codes considered medically necessary if criteria are met: | |
| <i>Code</i> | <i>Description</i> |
| G35 | Multiple sclerosis |
| K50.00 | Crohn's disease of small intestine without complications |
| K50.011 | Crohn's disease of small intestine with rectal bleeding |
| K50.012 | Crohn's disease of small intestine with intestinal obstruction |
| K50.013 | Crohn's disease of small intestine with fistula |
| K50.014 | Crohn's disease of small intestine with abscess |
| K50.018 | Crohn's disease of small intestine with other complication |
| K50.019 | Crohn's disease of small intestine with unspecified complications |
| K50.10 | Crohn's disease of large intestine without complications |
| K50.111 | Crohn's disease of large intestine with rectal bleeding |
| K50.112 | Crohn's disease of large intestine with intestinal obstruction |
| K50.113 | Crohn's disease of large intestine with fistula |
| K50.114 | Crohn's disease of large intestine with abscess |
| K50.118 | Crohn's disease of large intestine with other complication |
| K50.119 | Crohn's disease of large intestine with unspecified complications |
| K50.80 | Crohn's disease of both small and large intestine without complications |
| K50.811 | Crohn's disease of both small and large intestine with rectal bleeding |
| K50.812 | Crohn's disease of both small and large intestine with intestinal obstruction |
| K50.813 | Crohn's disease of both small and large intestine with fistula |
| K50.814 | Crohn's disease of both small and large intestine with abscess |
| K50.818 | Crohn's disease of both small and large intestine with other complication |
| K50.819 | Crohn's disease of both small and large intestine with unspecified complications |
| K50.90 | Crohn's disease, unspecified, without complications |
| K50.911 | Crohn's disease, unspecified, with rectal bleeding |

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| K50.912 | Crohn's disease, unspecified, with intestinal obstruction |
| K50.913 | Crohn's disease, unspecified, with fistula |
| K50.914 | Crohn's disease, unspecified, with abscess |
| K50.918 | Crohn's disease, unspecified, with other complication |
| K50.919 | Crohn's disease, unspecified, with unspecified complications |

References

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Clinical Guideline Revision / History Information

Original Date: 3/21/2024

Reviewed/Revised: 4/26/2024