

**Tysabri (natalizumab)
 Tyruko (natalizumab-sztn)
 Lemtrada (alemtuzumab)
 Effective 05/01/2026**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671	
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029	
Exceptions	N/A			

Overview

Tysabri (natalizumab) and its biosimilar Tyruko (natalizumab-sztn) are integrin receptor antagonists indicated for the treatment of:

- **Multiple sclerosis:** monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- **Crohn’s disease:** Inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn’s disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. In CD, Tysabri should not be used in combination with immunosuppressants or inhibitors of TNF-alpha.

Lemtrada (alemtuzumab) is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

OR

Authorization may be granted when all of the following diagnosis-specific criteria are met:

Multiple Sclerosis – Tysabri, Tyruko and Lemtrada

1. Member has one of the following diagnoses:
 - a. Clinically isolated syndrome (**Tysabri and Tyruko only**)
 - b. Relapsing-remitting disease
 - c. Active secondary progressive disease
2. Member is 18 years of age or older
3. Requested medication is prescribed by or in consultation with a neurologist
4. **For Lemtrada:** member has an inadequate response, adverse reaction or contraindication to BOTH of the following:
 - a. Tysabri or Tyruko
 - b. Ocrevus or Ocrevus Zunovo

Crohn’s Disease – Tyruko and Tysabri ONLY

1. Diagnosis of moderately to severely active Crohn’s disease
2. ONE of the following:
 - a. Member has had trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
 - i. 6-mercaptopurine
 - ii. Azathioprine
 - iii. Corticosteroids (e.g., prednisone)
 - iv. Methotrexate
 - b. Disease severity warrants systemic biologic as first-line therapy
3. Member has had a trial and failure, intolerance, or contraindication to a TNF-alpha inhibitor (e.g., certolizumab, adalimumab)

Continuation of Therapy

Requests for reauthorization will be approved when all of the following diagnosis-specific criteria are met:

1. **Multiple Sclerosis (Lemtrada and Tysabri and Tyruko):**
 - a. Submission of medical records (e.g., chart notes) documenting the member is experiencing disease stability or improvement with the requested medication
2. **Crohn’s disease (Tysabri and Tyruko):**
 - a. Submission of medical records (e.g., chart notes) documenting an improvement in the member’s condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Tysabri and Tyruko:
 - a. Initial approvals and reauthorizations will be granted for 12 months.
 - b. The following quantity limitations apply on the pharmacy benefit:

Drug Name and Dosage Form	Quantity Limit
Tysabri vial	1 vial per 28 days
Tyruko vial	1 vial per 28 days

2. Lemtrada:
 - a. Approval of 2 treatment courses in 24 months will be authorized. The first course is administered as 12mg/day on 5 consecutive days. The second course, given 12 months after the first course, is administered as 12mg/day on 3 consecutive days.



- b. Requests for subsequent treatments of 12mg/day for 3 consecutive days at least 12 months after the last treatment course, will require submission of medical necessity by the prescriber.

References

1. Clerico M, Artusi CA, Liberto AD, et al. Natalizumab in multiple sclerosis: long-term management. *Int J Mol Sci.* 2017;18(5). pii: E940 10.3390/ijms18050940
2. Lemtrada (alemtuzumab) [prescribing information]. Cambridge, MA: Genzyme Corporation; May 2024.
3. 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 [published correction appears in *Neurology.* 2019;92(2):112]. *Neurology.* 2018;90(17):777-788. 10.1212/WNL.0000000000005347
4. Tyruko (natalizumab-sztn) [prescribing information]. Princeton, NJ: Sandoz Inc; March 2023.
5. Tysabri (natalizumab) [prescribing information]. Cambridge, MA: Biogen Inc; March 2025.

Review History

11/18/2020- Updated- combined Tysabri and Lemtrada into one document, changed Tysabri to preferred product, Reviewed by P+T

11/17/2021 – Updated and reviewed Nov P&T; updated benefit type to pharmacy and medical. Effective 1/1/2022

07/11/2025 – Reviewed and updated at July P&T. Updated criteria for MS to specify that only Tysabri will be approved for CIS. Added Ocrevus Zunovo as a previous trial option for MS. Added specialist prescriber requirement to MS criteria. Updated reauthorization criteria. Effective 11/01/2025.

10/08/2025 – Reviewed and updated at October P&T. Updated policy to indicate that it no longer applies to the medical benefit. Effective 01/01/2026.

12/10/2025 – Reviewed and updated at November P&T. Added Tyruko to the policy. Effective 03/01/2026.

03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes...” and updating language for members who are new to the Plan. Effective 05/01/2026.

