Mass General Brigham
Health Plan

Tysabri (natalizumab)
Lemtrada (alemtuzumab)
Effective 01/01/2026

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

Overview

Tysabri (natalizumab) is an integrin receptor antagonist 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

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, 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 and Lemtrada

1. Member has one of the following diagnoses:
    a. Clinically isolated syndrome **(Tysabri 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
    b. Ocrevus/Ocrevus Zunovo

Crohn's Disease – 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 the following criteria are met:

1. **Multiple Sclerosis (Lemtrada and Tysabri):**
    a. Documentation member is experiencing disease stability or improvement with the requested medication
2. **Crohn's disease (Tysabri):**
    a. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Tysabri:
    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

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. 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.