Mass General Brigham
Health Plan

Tysabri (natalizumab)
Lemtrada (alemtuzumab)
Effective 01/01/2022

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Tysabri and Lemtrada are monoclonal antibody disease-modifying drugs. Tysabri is indicated for relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome (CIS), relapsing-remitting (RRMS) and active secondary progressive (SPMS) in adults. Tysabri is also indicated for 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-α. Lemtrada is indicated for RRMS and SPMS in adults

Coverage Guidelines
Authorization may be granted for members new to the plan who are currently receiving treatment with Tysabri or Lemtrada excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members for Tysabri or Lemtrada when the following criteria are met, and documentation is provided:

Multiple Sclerosis - Tysabri and Lemtrada
1. The member is diagnosed with a relapsing form of MS, including RRMS, CIS or active SPMS
2. The member is ≥ 18 years of age
3. **For Lemtrada**, the member has an inadequate response, adverse reaction or contraindication to Tysabri AND Ocrevus.

Crohn's Disease – Tysabri ONLY
1. The member is diagnosed with a moderate to severely active Crohn's disease
2. The member is ≥ 18 years of age
3. The member has had previous use of any biologic agent

4. The member is NOT using Tysabri with an immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-α.

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition.

Limitations

1. All indications for Tysabri, approvals for will be authorized for 12 months
2. For Lemtrada, 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. 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. Lemtrada (alemtuzumab) [prescribing information]. Cambridge, MA: Genzyme Corporation; May 2020.
2. 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
3. Tysabri (natalizumab) [prescribing information]. Cambridge, MA: Biogen Inc; June 2020.
4. 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

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

References

Opdualag [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.