Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/12/2023

Lemtrada® (alemtuzumab)

HCPCS: J0202

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. FDA approved indication
   c. Will not be used in combination with other disease-modifying treatments of multiple sclerosis (MS)
   d. Coverage will be provided for biosimilar products for FDA labeled indications of the innovator product when criteria are met.
   e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limitations: Align with FDA recommended dosing and duration of treatment.
   b. Authorization Period: One year at a time.
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit, such as disease stability or improvement.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Multiple sclerosis (MS) is a chronic progressive inflammatory autoimmune disease of the central nervous system, involving axonal deterioration and demyelination. Signs and symptoms vary greatly and can include blurry or double vision, muscle weakness and stiffness, tingling in limbs, fatigue, difficulty concentrating, and many other debilitating

symptoms. MS typically presents between the ages of 20 and 45, and women are affected by MS three times more frequently than men. Onset of symptoms before age 21 occurs in 3-5% of cases and is considered juvenile MS.

- Several clinical presentations of MS have been identified including relapsing-remitting MS (RRMS), secondary progressive MS (SPMS), primary progressive MS (PPMS), and a rare form called progressiverelapsing (PRMS). All forms of MS are associated with neurologic dysfunction. Relapsing-remitting MS affects the majority of newly diagnosed individuals and about half of the people diagnosed with RRMS will transition to SPMS within 10-20 years of initial diagnosis. Relapses are characterized as periods of sudden worsening of symptoms or new symptoms.Often, the periods of remission between relapses will last weeks, months, or even years.

- Patients diagnosed with PPMS experience continued and gradual physical decline without remissions. Primary progressive MS affects as many men as women and typically presents after the age of 40. Progressive-relapsing MS affects only about 5% of patients diagnosed with MS and is characterized by steady worsening dysfunction with distinct exacerbations.

- The American Academy of Neurology (AAN) 2018 treatment guidelines for adults with MS state that there are a variety of disease modifying therapies (DMTs) available; therefore, evaluating patient preference may improve acceptance and adherence to DMT. Considerations when choosing DMT include safety, route of administration, lifestyle, cost, efficacy, common adverse effects, tolerability, comorbid conditions, and concomitant medications. Recommendations for first-line therapy are not specified, with the exception of Lemtrada (alemtuzumab), Tysabri (natalizumab), and Gilenya (fingolimod) for highly active MS and Ocrevus (ocrelizumab) for primary progressive MS.

- There are no formal guidelines for the treatment of pediatric MS which is rare. Less than 5,000 children and teens are living with MS in the United States. Pediatric patients with MS typically experience more frequent relapses compared to adults with MS but recover from relapses more quickly than adults. Although Gilenya and Tascenso ODT are the only approved therapies for pediatric MS, many of the disease modifying therapies prescribed for adults with MS are also prescribed for pediatric MS based on supporting data such as small retrospective studies and case studies.

References:

1. Drug Facts and Comaprisons. eFacts (online). 2022. Available from Wolters Kluwer Health, Inc. Accessed January 3, 2023.
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. Neurology. 2018;90:777-788. Available at: https://n.neurology.org/content/neurology/90/17/777.full.pdf. Accessed on January 3, 2023.
3. Lotze TE. Treatment and prognosis of pediatric multiple sclerosis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on January 3, 2023). Page 218 of 421 P&T OCT2023
4. National Multiple Sclerosis Society. Pediatric MS. Available at: https://www.nationalmssociety.org/ForProfessionals/Clinical-Care/Managing-MS/Pediatric-MS. Accessed on January 3, 2023.
5. IPD Analytics. Payer & Provider Insights. January 2022. Accessed January 3, 2023. https://www.ipdanalytics.com

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.4</td><td>Effective Date: 10/12/2023</td><td>Updated policy to include Tyruko (natalizumab-sztn)
Added criteria for biosimilar products</td></tr>
<tr><td>2.3</td><td>Effective Date: 02/02/2023</td><td>Updated policy to include Briumvi</td></tr>
<tr><td>2.2</td><td>Effective Date: 10/06/2022</td><td>Added Mavenclad and generic Copaxone back to policy</td></tr>
<tr><td>2.1</td><td>Effective Date: 02/10/2022</td><td>Added Tascenso to the policy</td></tr>
<tr><td>2.0</td><td>Effective Date: 06/10/2021</td><td>Added Ponvory to policy and removed prescriber requirement.</td></tr>
<tr><td>1.9</td><td>Effective Date: 10/08/2020</td><td>Added Kesimpta to policy</td></tr>
<tr><td>1.8</td><td>Effective Date: 10/01/2019</td><td>UM medical management system update for BCBSM and BCN
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.7</td><td>Effective Date: 08/15/2019</td><td>Updated criteria for Ocrevus, Lemtrada, and Tysabri to be just indication only
After MBDC: Removed investigational use sections from drug specific criteria due to updated indications for many MS medications</td></tr>
<tr><td>1.6</td><td>Effective Date: 02/14/2019</td><td>Updated quantity limit for Lemtrada</td></tr>
<tr><td>1.5</td><td>Effective date: 08/09/2018</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.4</td><td>Effective Date: 07/01/2018</td><td>UM medical management system update to be removed
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.3</td><td>Effective Date: 08/10/2017</td><td>Added criteria for Ocrevus and updated criteria Lemtrada, and Tysabri</td></tr>
<tr><td>1.2</td><td>Effective Date: 11/10/2016</td><td>Added Zinbryta</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/11/2016</td><td>Updated MD attestation and Lemtrada QL</td></tr>
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<tr>
<td>1.0</td>
<td>Effective Date:
08/13/2015</td>
<td>New Policy
<table>
<tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Lemtrada® (alemtuzumab) HCPCS CODE: J0202

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This form is to be used by participating physicians to obtain coverage for Lemtrada®. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION		PHYSICIAN INFORMATION
Name		**Name**
ID Number		**Specialty**
D.O.B.	☐Male ☐Female	**Address**
Patient weight (in kg)	Date recorded:_____	
Diagnosis		**City /State/Zip**
Drug Name		**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity		**NPI**
Directions		**Contact Person**
Date of Service(s)		**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Initiation or Continuation of treatment? ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #3) *Reason for Hospital Outpatient:* _____
3. Please specify location of administration if hospital outpatient infusion: _____
4. Please provide the NPI number for the place of administration: _____
5. Indicate which course of therapy this request is for? ☐ First course ☐ Second course ☐ Third or more course
6. **Initiation AND Continuation of Therapy:**
   a. Please check the patient's diagnosis:
      ☐ Relapsing-Remitting Multiple Sclerosis (RRMS)
      ☐ Active Secondary Progressive multiple sclerosis
      ☐ Other: _____
7. **Continuation Request** (please answer questions above as well): Lemtrada start date: _____
   a. How has the patient improved while on Lemtrada? (check all that apply)
      ☐ Slowing of disability progression
      ☐ No new T1/T2 lesions
      ☐ Decrease in frequency of relapses
      ☐ Improvement in disability
      ☐ Other: _____
8. Will the patient be using Lemtrada used in combination with other disease-modifying treatments for multiple sclerosis (MS) (for example: Ocrevus)?
   ☐ Yes, comment: _____ ☐ No

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	**Physician Signature**	**Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ Concurrent Medical Problems ☐ Prior Therapies
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

4/9/2015; 11/20/2015; 8/11/2017; 2/2/2018;10/11/2018; 2/26/2020