Blue Cross Blue Shield Blue Care Network of Michigan

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Retired
Effective Date: 10/12/2023

Lumoxiti™ (moxetumomab pasudotox-tdfk)

HCPCS: J9313

Policy:

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

A. Criteria:
   a. FDA approved indication
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist
   d. Must have received at least 2 prior systemic therapies, one of which is a purine nucleoside analog
   e. Creatinine clearance must be greater than or equal to 30 mL/min
   f. For use as monotherapy only
   g. Limited to a single line of therapy

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time

***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

- Lumoxiti is a CD22-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA). Use is not recommended in patients with severe renal impairment with a creatinine clearance less than or equal to 29 mL/min.

- The efficacy of Lumoxiti was studied in a single-arm, open-label clinical trial of 80 patients with histologically confirmed HCL who had received prior treatment with at least two systemic therapies, including a purine nucleoside analog. The mean number of prior therapies was 3 with a range of 2 – 11. All patients had received a purine nucleoside analog and the most common other therapies included Rituxan monotherapy, interferon-alpha, and a BRAF inhibitor. Patient received Lumoxiti monotherapy at a dose of 0.04 mg/kg on days 1, 3, and 5 of a 28 day treatment cycle for a maximum of 6 cycles. Efficact evaluations were performed by an independent review committee using blood, bone marrow, and imaging criteria adapted from previous studies and concensus guidelines. Durable complete response (CR) was confirmed by maintenance of hematological remission (hemoglobin ≥ 11 g/dL, neutrophils ≥ 1500/mm^3, and platelets > 100,000/mm^3 without blood transfusion or growth factor for at least 4 weeks) more than 180 days after confirmed CR. The durable complete response was 30%.

- Lumoxiti has not been studied in combination with other therapies and should only be used as monotherapy.

- The National Comprehensive Cancer Network 2022 treatment guidelines for hairy cell leukemia do not recommend use of Lumoxiti following a prior treatment failure and limits use to a single line of therapy.

References:

1. Lumoxiti [prescribing information]. Wilmington DE: AstraZeneca; February 2022.
2. National Comprehensive Cancer Network. Hairy cell leukemia (Version 1.2023). 2022 August 30. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf. Accessed on January 27, 2023
3. Troussard, X, Montané, L, Tiab, M, et al. Vemurafenib in advanced patients with hairy cell leukemia (HCL): results of the acsé phase II trial. Blood. 2017; 130 (Suppl 1): 156.
4. Jones, J, Andritsos, L, Kreitman, RJ, et al. Efficacy and safety of the bruton tyrosine kinase inhibitor ibrutinib in patients with hairy cell leukemia: stage 1 results of a phase 2 study. Blood. 2016; 128 (22): 1215.
5. Kreitman RJ, Dearden C, Zinzani PL, et al. Moxetumomab pasudotox in relapsed/refractory hairy cell leukemia. Leukemia. 2018 July 20; 32: 1768 – 77.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.9</td><td>Effective Date: 10/12/2023</td><td>Policy is being retired as medication has been removed from the market by the manufacturer</td></tr>
<tr><td>1.8</td><td>Effective Date: 04/06/2023</td><td>Updated approval length to allow for at least a 60 day approval duration</td></tr>
<tr><td>1.7</td><td>Effective Date: 10/06/2022</td><td>Updated approval length to allow for FDA recommended dosing or up to 6 months at a time</td></tr>
<tr><td>1.6</td><td>Effective Date: 10/07/2021</td><td>Annual review – no changes to the criteria at this time.</td></tr>
<tr><td>1.5</td><td>Effective Date: 12/01/2020</td><td>UM medical management system update for BCBS
<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>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.4</td><td>Effective Date: 10/08/2020</td><td>Annual Review</td></tr>
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<tr><td>1.3</td><td>Effective Date: 3/16/2020</td><td>UM medical management system update for MAPPO and BCNA
<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>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.2</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 10/01/2019</td><td>UM medical management system update for BCN
<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>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effective Date: 11/01/2018</td><td>New Policy
<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>
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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.*