Blue Cross Blue Shield Blue Care Network of Michigan

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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.

Retired
Effective Date: 02/02/2023

Marqibo®(vincristine sulfate liposome)

HCPCS: J9370

Policy:

Request 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. Diagnosis of Philadelphia chromosome negative acute lymphoblastic leukemia (ALL) with greater than or equal to 2 relapses following two or more anti-leukemia therapies
   c. Diagnosis of Philadelphia chromosome positive ALL for relapse or refractory disease following tyrosine kinase inhibitor therapy
   d. Prescribed by or in consultation with an oncologist or hematologist

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 up to 6 months at a time
   c. Renewal Criteria: Continuation of therapy until disease progression or unacceptable toxicity

***Note: Coverage 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:

- Marqibo is indicated for the treatment adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies.

- Safety and efficacy were evaluated in a phase 2, international, open-label, multi-center, single-arm trial of 65 adults with Philadelphia chromosome negative ALL in second or greater relapse or whose disease had progressed following

two or more leukemia therapies. Patients received Marqibo 2.25 mg/m^2 once weekly until response, progression, toxicity, or pursuit of HCT. The primary end point was achievement of complete response (CR) or CR with incomplete hematologic recovery (CRi). The CR/CRi rate was 20% and overall response rate was 35%. Vincristine sulfate liposome injection monotherapy was effective as third-, fourth-, and fifth-line therapy and in patients refractory to other single- and multiagent reinduction therapies. Median CR/CRi duration was 23 weeks (range, 5 to 66 weeks.

- Marqibo is also used off-label in Philadelphia chromosome positive ALL that is relapsed or refractory following tyrosine kinase inhibitor therapy. Due to the rarity of Philadelphia chromosome positive ALL, data for use of inm this indication is extrapolated as once patients with Philadephia chromosome positive ALL fail TKI therapy, they are treated as Philadelphia chromosome negative ALL patients in clinical practice.

References:

1. Marqibo [prescribing information]. South San Francisco, CA: Talon Pharmaceuticals Inc.; June 2020.
2. National Comprehensive Cancer Network. Acute lymphoblastic leukemia (Version 1.2022). 2022 April 4. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed on August 22, 2022.
3. Hunault-Berger M, Leguay T, Thomas X, et al. With the drug schedules used in this study, pegylated liposomal doxorubicin did not improve the outcome of elderly patients with acute lymphoblastic leukemia despite reduced toxicities. Haematologica. 2011 Feb; 96 (2): 245 - 52.
4. Hagemeister F, Rodriguez MA, Deitcher SR, et al. Long term results of a phase 2 study of vincristine sulfate liposome injection (Marqibo(®)) substituted for non-liposomal vincristine in cyclophosphamide, doxorubicin, vincristine, prednisone with or without rituximab for patients with untreated aggressive non-Hodgkin lymphomas. Br J Haematol. 2013 Sep; 162 (5): 631 - 8.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.8</td><td>Effective Date: 02/02/2023</td><td>Retiring policy as drug will no longer be part of the prior authorization program</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 of criteria was performed, no changes were made.</td></tr>
<tr><td>1.5</td><td>Effective Date: 10/08/2020</td><td>Annual Review</td></tr>
<tr><td>1.4</td><td>Effective Date: 11/07/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.3</td><td>Effective Date: 11/01/2018</td><td>Updated criteria per oncology vendor</td></tr>
<tr><td>1.2</td><td>Effective Date: 08/09/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/10/2017</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.0</td><td>Effective Date: 11/2012</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>
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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.*