Coverage of any drug intervention discussed in a WellFirst Health prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

Marqibo® (vincristine sulfate liposomal)

(Intravenous)

Document Number: IC-0159

Last Review Date: 07/20/2022

Date of Origin: 02/07/2013

Dates Reviewed: 12/2013, 02/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 01/2019, 01/2020, 01/2021, 01/2022, 07/2022

Effective Date: 01/01/2023

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Marqibo 5 mg/31 mL liposome injection kit: 8 vials every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 40 billable units every 28 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; AND

Universal Criteria [1]

- Patient does not have any pre-existing demyelinating conditions (e.g., Charcot-Marie-Tooth Syndrome); AND

Acute Lymphoblastic Leukemia (ALL) † Φ [1-3]

- Used as single agent therapy; AND
- Used for relapsed or refractory disease; AND

Proprietary & Confidential

© 2022 Magellan Health, Inc.

- Patient has Philadelphia chromosome-negative (Ph-) disease; **OR**
- Patient has Philadelphia chromosome-positive (Ph+) B-ALL and is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, ponatinib, etc.) ‡

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: extravasation tissue injury, peripheral motor and sensory neuropathy, central and autonomic neuropathy, myelosuppression (e.g., neutropenia, thrombocytopenia, or anemia), tumor lysis syndrome, constipation and bowel obstruction, severe fatigue, elevated liver function tests (ALT, AST, and bilirubin), etc.; **AND**
- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

V. Dosage/Administration [1]

Indication	Dose
Acute Lymphocytic Leukemia (ALL)	Administer 2.25 mg/m^2 intravenously over 1 hour once every 7 days. • NOT for intrathecal use *(intravenous use only)*

VI. Billing Code/Availability Information

HCPCS Code:

- J9371 – Injection, vincristine sulfate liposome, 1 mg; 1 mg = 1 billable unit

NDC:

- Marqibo 5 mg/31 mL liposome injection kit: 72893-0008-xx

VII. References

1. Marqibo [package insert]. East Windsor, NJ; Acrotech Biopharma LLC; June 2020. Accessed November 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for vincristine sulfate liposome. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2022, Magellan Rx Management

recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Acute Lymphoblastic Leukemia 2.2021. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2021.
4. O'Brien S, Schiller G, Lister J, et al. High-dose vincristine sulfate liposome injection for advanced, relapsed, and refractory adult Philadelphia chromosome-negative acute lymphoblastic leukemia. J Clin Oncol. 2013 Feb 20;31(6):676-83. doi: 10.1200/JCO.2012.46.2309.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck
C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C91.00	Acute lymphoblastic leukemia, not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2022, Magellan Rx Management

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2022, Magellan Rx Management