



Marqibo® (vincristine sulfate liposomal)

Document Number: IC-0159

Last Review Date: 11/21/2017

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

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

- 40 billable units every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Patient does not have any pre-existing demyelinating conditions (e.g. Charcot-Marie-Tooth Syndrome); **AND**

Acute Lymphoblastic Leukemia (ALL) †

- Used as single agent therapy; **AND**
- Used for relapsed or refractory disease; **AND**
 - Patient's disease is Philadelphia chromosome-negative (Ph⁻); **OR**
 - Patient's disease is Philadelphia chromosome-positive (Ph⁺) and refractory to tyrosine kinase inhibitor therapy

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**

- Stabilization of disease and/or absence of progression of disease; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: peripheral motor and sensory, central and autonomic neuropathy; myelosuppression; neutropenia; thrombocytopenia; anemia; tumor lysis syndrome; elevated liver function tests (ALT, AST, and bilirubin).

V. Dosage/Administration

Indication	Dose
Acute Lymphocytic Leukemia (ALL)	2.25 mg/m ² intravenously over 1 hour once every 7 days

VI. Billing Code/Availability Information

Jcode:

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

NDC:

- Marqibo 5 mg/31 mL liposome injection kit: 20536-0322-xx

VII. References

1. Marqibo [package insert]. San South San Francisco, CA: Talon Therapeutics; November 2016. Accessed October 2017.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for vincristine sulfate liposomal. National Comprehensive Cancer Network, 2017. 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 October 2017.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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): N/A

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	Cahaba Government Benefit Administrators, 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