

Marqibo® (vincristine sulfate liposomal)

Last Review Date: May 1st, 2018

Number: MG.MM.PH.49

Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Marqibo (vincristine sulfate liposomal) is a sphingomyelin/cholesterol liposome-encapsulated formulation of vincristine sulfate. Non-liposomal vincristine sulfate binds to tubulin, altering the tubulin polymerization equilibrium, resulting in altered microtubule structure and function. Non-liposomal vincristine sulfate stabilizes the spindle apparatus, preventing chromosome segregation, triggering metaphase arrest and inhibition of mitosis.

Marqibo (vincristine sulfate liposomal) is a vinca alkaloid indicated for the treatment of adult patients with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. The drug is for intravenous use only. Marqibo is contraindicated for intrathecal administration.

Marqibo (vincristine sulfate liposomal) has different dosage recommendations than vincristine sulfate injection. Drug name and dose must be verified prior to preparation and administration to avoid overdose.

Dosing

Max Units (per dose and over time):

- 40 billable units every 28 days

Guideline

Marqibo (vincristine sulfate liposomal) is considered medically necessary for the following diagnosis when all of the following criteria are met:

Relapsed or progressed Acute Lymphoblastic Leukemia (ALL)

- Patient is at least 18 years old; **AND**
- Patient's disease is Philadelphia chromosome-negative (Ph-)
 - Patient's disease is in second or greater relapse; **OR**
 - Patient's disease has progressed following two or more anti-leukemia therapies; **AND**
- Patient does not have any pre-existing demyelinating conditions (e.g. Charcot-Marie-Tooth Syndrome); **AND**
- Marqibo is being used as single agent therapy

Coverage for Marqibo (vincristine sulfate liposomal) may be renewed when the following criteria are met:

- Stabilization 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).

Limitations/Exclusions

- Approval will be granted for six months and may be renewed

Applicable Procedure Codes

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

Applicable Diagnosis Codes

C91.00	Acute lymphoblastic leukemia, not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

References

1. Marqibo [package insert]. San South San Francisco, CA: Talon Therapeutics; November 2016. Accessed December 2017.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for vincristine sulfate liposomal. National Comprehensive Cancer Network, 2018. 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 December 2018.