Vincristine Sulfate Liposome Injection (Marqibo®)

NDC CODE(S) 72893-0008-XX MARQIBO 5MG/31ML Suspension (ACROTECH BIOPHARMA)

DESCRIPTION

Vincristine sulfate is a vinca alkaloid isolated from the periwinkle plant (*Catharanthus roseus*). Non-liposomal vincristine sulfate binds to tubulin within cells resulting in altered microtubule structure and function. It stabilizes the cellular spindle apparatus and prevents chromosome segregation leading to metaphase arrest and inhibits mitosis. By encapsulating vincristine in sphingomyelin/cholesterol liposomes, the plasma clearance is slowed and the vincristine sulfate remains active longer in the body.

POLICY

- Vincristine sulfate liposome injection for the treatment of acute lymphoblastic leukemia (ALL) is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Vincristine sulfate liposome injection for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age; **AND**
- Prior trial and failure of Vincristine is required; **AND**

Universal Criteria
- 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 (e.g., imatinib, dasatinib, nilotinib, ponatinib, etc.)

RENEWAL 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 initial approval criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: 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

DOSAGE/ADMINISTRATION

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)

LENGTH OF AUTHORIZATION

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

DOSAGE LIMITS

Max Units (per dose and over time) [HCPCS Unit]:
- 40 billable units every 28 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Marqibo [package insert]. East Windsor, NJ; Acrotech Biopharma LLC; June 2020. Accessed November 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for vincristine sulfate liposome. National Comprehensive Cancer Network, 2020. 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 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Acute Lymphoblastic Leukemia 2.2020. National Comprehensive Cancer Network, 2020. 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 2020.
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.
5. Lexicomp Online. (2020, March). AHFS. *Vincristine sulfate liposomal.* Retrieved January 12, 2021 from Lexicomp Online with AHFS.
6. **M**ICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, November). *Vincristine sulfate liposome.* Retrieved January 12, 2021 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 6/2/2021

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