Vincristine Sulfate Liposome Injection

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

- Vincristine sulfate liposome injection is considered **medically appropriate** if **ALL** of the following criteria are met:
  - Individual is 18 years of age or older
  - **BCBST requirement:** Prior trial and failure of Vincristine is required
  - Individual does not have any pre-existing demyelinating conditions (e.g. Charcot-Marie-Tooth Syndrome)
  - Diagnosis of Acute Lymphoblastic Leukemia (ALL) which is **ALL** of the following
    - Used as single agent therapy
    - In relapsed or refractory disease and **ANY ONE** of the following:
      - Philadelphia chromosome-negative (Ph-)
      - Philadelphia chromosome-positive (Ph+) **AND** refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, ponatinib, etc.)

RENEWAL CRITERIA

- Vincristine sulfate liposome injection is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet initial approval criteria
  - Response to treatment is indicated by stabilization of disease and/or absence of progression of disease
  - Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: peripheral motor and sensory neuropathy, central and autonomic neuropathy, myelosuppression (e.g., neutropenia; thrombocytopenia; or anemia), tumor lysis syndrome, elevated liver function tests (ALT, AST, and bilirubin), etc.

INDICATION(S)	DOSAGE & ADMINISTRATION

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.

Refer to **DOSAGE LIMITS** below

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

Lexicomp Online. (2020, March). AHFS. *Vincristine sulfate liposomal.* Retrieved December 8, 2020 from Lexicomp Online with AHFS.

MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, November). *Vincristine sulfate liposome.* Retrieved December 8, 2020 from MICROMEDEX Healthcare Series.

National Comprehensive Cancer Network. (2020). NCCN Drugs & Biologics Compendium®. *Vincristine sulfate liposome injection.* Retrieved December 2, 2020 from the National Comprehensive Cancer Network.

U. S. Food and Drug Administration. (2020, June). Center for Drug Evaluation and Research. *Marqibo® (vincristine sulfate liposome injection) for intravenous infusion.* Retrieved December 2, 2020 from http://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202497s000lbl.pdf.

BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual **Approved Revision: Do Not Implement Until 4/2/21**

EFFECTIVE DATE 4/2/21

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