

Vincristine Sulfate Liposome (Marqibo®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020

Revision Date: n/a

Review Date: 10/4/2021

Lines of Business: Commercial

Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of vincristine sulfate liposome. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description¹

Vincristine sulfate liposome 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.

FDA Indication¹

Vincristine sulfate liposome is FDA indicated for the following:

- Treatment of adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies

Coverage Determinations^{1,2}

Vincristine sulfate liposome will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Acute Lymphoblastic Leukemia (ALL)

- The member has a diagnosis of Philadelphia chromosome-negative ALL **AND**
- The member has relapsed/refractory disease that meets one of the following:

Vincristine sulfate liposome

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- In second or greater relapse **OR**
- Progression following two or more lines of anti-leukemia therapies **AND**
- Vincristine sulfate liposome will be used as monotherapy

Recommended dosage: 2.25 mg/m² IV over 1 hour once every 7 days

All indications:

- Vincristine sulfate liposome will be approved through clinical review for up to a 12-month duration

Coverage Limitations

Treatment with vincristine sulfate liposome is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on vincristine sulfate liposome.
- The member has treatment-naïve Philadelphia chromosome-negative ALL.
- The member has Philadelphia chromosome-positive ALL.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions¹

- Vincristine sulfate liposome is contraindicated:
 - In patients with demyelinating conditions including Charcot-Marie-Tooth syndrome
 - In patients with hypersensitivity to vincristine sulfate or any of the other components of Vincristine sulfate liposome
 - For intrathecal administration
- Warnings/Precautions:
 - Intrathecal Administration
 - Extravasation
 - Neurologic Toxicity
 - Myelosuppression
 - Tumor Lysis Syndrome
 - Constipation, Bowel Obstruction, and/or Paralytic Ileus
 - Fatigue
 - Hepatic Toxicity
 - Embryofetal Toxicity

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: inj., vincristine sulfate liposome, 1 mg
 - HCPCS: J9371

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Marqibo® [package insert]. Acrotech Biopharma LLC, East Windsor, NJ. Available at: <https://marqibo.com/hcp/wp-content/uploads/2019/11/PI-MARQIBO-092019.pdf>
2. Vincristine sulfate liposome. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. 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):676-683. DOI: 10.1200/JCO.2012.46.2309.