

Marqibo® (vincristine sulfate liposome injection)



Pharmacy Coverage Policy

Effective Date: January 01, 2020

Revision Date: August 18, 2021

Review Date: August 17, 2022

Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio

Policy Type: Prior Authorization

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at <http://www.cms.hhs.gov/>. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

Description

Marqibo (vincristine sulfate liposome injection) is sphingomyelin/cholesterol liposome-encapsulated formulation of vincristine sulfate for intravenous administration.

Marqibo (vincristine sulfate liposome injection) is indicated for the treatment 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. This indication is based on overall response rate. Clinical benefit such as improvement in overall survival has not been verified.

Vincristine sulfate liposome injection is available as the Marqibo Kit.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are

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subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Marqibo (vincristine sulfate liposome injection) will require medical prior authorization. This agent may be considered medically necessary when the following criteria are met:

Acute Lymphoblastic Leukemia

- The member has a diagnosis of relapsed/refractory Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL) **OR**
- The member has a diagnosis of Philadelphia chromosome-positive (Ph+) disease that is refractory to tyrosine kinase inhibitor therapy **AND**
- Marqibo will be used as a single-agent salvage therapy **AND**
- The member has had disease progression following vincristine sulfate* **AND**
- One of the following applies:
 - The member is beyond second relapse **OR**
 - The member has had disease progression following two or more therapies

*For Medicare Part B requests, the step therapy requirement does not apply if the

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request is a continuation of prior therapy within the past 365 days.

Marqibo (vincristine sulfate liposome injection) will be approved in six month durations or as determined through clinical review.

Coverage Limitations

Marqibo (vincristine sulfate liposome injection) therapy is not considered medically necessary for members with the following concomitant conditions:

- Members who have experienced disease progression on Marqibo (vincristine sulfate liposome injection)
- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Marqibo (vincristine sulfate liposome injection).

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

Contraindications:

- Marqibo (vincristine sulfate liposome injection) is contraindicated in patients with demyelinating conditions including Charcot-Marie-Tooth syndrome
- Marqibo (vincristine sulfate liposome injection) is contraindicated in patients with hypersensitivity to vincristine sulfate or any of the other components

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- Marqibo (vincristine sulfate liposome injection) is contraindicated for intrathecal administration

Warnings and Precautions:

- For intravenous use only: Fatal if given by other routes. Death has occurred with intrathecal use.
- Extravasation tissue injury
- Neurologic Toxicity
- Myelosuppression
- Tumor Lysis Syndrome .
- Constipation
- Fatigue:
- Hepatic Toxicity
- Embryofetal toxicity

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

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Medical Terms Marqibo; vincristine sulfate liposome injection; acute lymphoblastic leukemia; intravenous infusion; medical

- References**
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 3. Marqibo [prescribing information]. Talon Therapeutics, Inc. South San Francisco, CA. June 2020.
 4. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Colorado 2021.
 5. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2021.