

## Clinical Policy: Vincristine Sulfate Liposome Injection (Marqibo)

Reference Number: CP.PHAR.315

Effective Date: 02/17

Last Review Date: 02/17

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for vincristine sulfate liposome injection (Marqibo®).

### Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Marqibo is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Acute Lymphoblastic Leukemia (must meet all):

1. Diagnosis of acute lymphoblastic leukemia (ALL):
2. Disease has relapsed  $\geq 2$  times or has progressed following  $\geq 2$  anti-leukemia therapies;
3. Meets a or b:
  - a. FDA approved use:
    - i. ALL is Philadelphia chromosome-negative;
  - b. Off-label NCCN recommended use (i and ii):
    - i. ALL is Philadelphia chromosome-positive and refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib);
    - ii. Marqibo is prescribed as single-agent therapy;
4. Member has none of the following contraindications:
  - a. Disease progression or unacceptable toxicity;
  - b. Demyelinating condition such as Charcot-Marie-Tooth syndrome;
  - c. Known hypersensitivity to vincristine sulfate or any of the other components of Marqibo;
  - d. Intrathecal administration.

**Approval duration: 3 months**

##### B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

#### II. Continued Approval

##### A. Acute Lymphoblastic Leukemia (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member has none of the following reasons to discontinue:
  - a. Peripheral neuropathy\* that remains at or increases to Grade 3\*\* (severe) or Grade 4\*\* (life-threatening) despite therapy interruption.

### Vincristine sulfate liposome injection

*\*Symptoms of sensory and motor neuropathies may include hypoesthesia, hyperesthesia, paresthesia, hyporeflexia, areflexia, neuralgia, jaw pain, decreased vibratory sense, cranial neuropathy, ileus, burning sensation, arthralgia, myalgia, muscle spasm, weakness before and during treatment; orthostatic hypotension also may occur.*

*\*\*Grading is based on the Common Terminology Criteria for Adverse Events*

#### **Approval duration: 6 months**

#### **B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

#### **Background**

##### *Description/Mechanism of Action:*

Marqibo 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.

##### *Formulations:*

The Marqibo Kit contains:

- Vial containing VinCRISTine Sulfate Injection, USP 5 mg/5 mL (1 mg/mL)
- Vial containing Sphingomyelin/Cholesterol Liposome Injection 103 mg/mL
- Vial containing Sodium Phosphate Injection 355 mg/25 mL (14.2 mg/mL)
- Flotation ring
- Overlabel for Sodium Phosphate Injection vial containing constituted Marqibo (vinCRISTine sulfate LIPOSOME injection), 5 mg/31 mL (0.16 mg/mL)
- Infusion bag label

##### *FDA Approved Indications:*

Marqibo is a vinca alkaloid/intravenous formulation indicated for:

- 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.
  - This indication is based on overall response rate. Clinical benefit such as improvement in overall survival has not been verified.

#### **Appendices**

##### **Appendix A: Abbreviation Key**

ALL: Acute lymphoblastic leukemia

#### **Coding Implications**

## CLINICAL POLICY

### Vincristine sulfate liposome injection

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9371	Injection, vincristine sulfate liposome, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Policy split from CP.PHAR.182.Excellus Oncology. NCCN recommended uses added.	01/17	02/17

#### References

1. Marqibo prescribing information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; July 2015. Available at <http://www.marqibo.com/pi/>. Accessed January 17, 2017.
2. Vincristine sulfate, liposome injection. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 17, 2017.
3. Acute lymphoblastic leukemia (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 17, 2017.

#### Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and

## CLINICAL POLICY

### Vincristine sulfate liposome injection

regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.