

Clinical Policy: Vincristine Sulfate Liposome Injection (Marqibo)

Reference Number: CP.PHAR.315

Effective Date: 02.17

Last Review Date: 11.17

Line of Business: Medicaid

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

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

Description

Vincristine sulfate liposome injection (Marqibo[®]) is a vinca alkaloid.

FDA Approved Indication(s)

Marqibo is indicated for the treatment of 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.

Limitation(s) of use: This indication is based on overall response rate. Clinical benefit such as improvement in overall survival has not been verified.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval 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 ALL:
2. Disease has relapsed ≥ 2 times or has progressed following ≥ 2 anti-leukemia therapies;
3. Meets a or b:
 - a. FDA-approved use:
 - i. ALL is Ph-negative;
 - b. Off-label NCCN recommended use (i and ii):
 - i. ALL is Ph-positive and refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib);
 - ii. Marqibo is prescribed as single-agent therapy;
4. Request meets one of the following (a or b):
 - a. Dose does not exceed 2.25 mg/m² every 7 days;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

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B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acute Lymphoblastic Leukemia (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., no disease progression, no significant toxicity);
3. If request is for a dose increase, new request meets one of the following (a or b):
 - a. New dose does not exceed 2.25 mg/m² every 7 days;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network

Appendix B: General Information

- 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ALL	2.25 mg/m ² IV over 1 hour once every 7 days	See dosing regimen

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VI. Product Availability

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

VII. References

1. Marqibo prescribing information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; July 2015. Available at <http://www.marqibo.com/pi/>. Accessed August 30, 2017.
2. Vincristine sulfate, liposome injection. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed August 30, 2017.

Coding Implications

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	P&T Approval Date
Policy split from CP.PHAR.182.Excellus Oncology. NCCN recommended uses added.	01.17	02.17
Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively.	08.30.17	11.17

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

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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 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.

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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.

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