

Clinical Policy: Vincristine Sulfate Liposome Injection (Marqibo)

Reference Number: PA.CP.PHAR.315

Effective Date: 01/18

Last Review Date: 11/17

[Coding Implications](#)

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Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness[®] clinical policy for vincristine sulfate liposome injection (Marqibo[®]).

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness[®] 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 ≥ 2 times or has progressed following ≥ 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. Demyelinating condition such as Charcot-Marie-Tooth syndrome;
 - b. Known hypersensitivity to vincristine sulfate or any of the other components of Marqibo;
 - c. Intrathecal administration.

Approval duration: 3 months

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

II. Continued Approval

A. Acute Lymphoblastic Leukemia (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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.

*Symptoms of sensory and motor neuropathies may include hypoesthesia, hyperesthesia, paresthesia, hyporeflexia, areflexia, neuralgia, jaw pain, decreased vibratory sense, cranial neuropathy, ileus, burning

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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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.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

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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

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.