Clinical Policy: Vincristine Sulfate Liposome Injection (Marqibo)

Reference Number: ERX.SPA.258
Effective Date: 12.01.18
Last Review Date: 11.18 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. 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. For members with Ph- ALL, disease has relapsed ≥ 2 times or has progressed following ≥ 2 anti-leukemia therapies;
   b. For members with Philadelphia chromosome-positive (Ph+) ALL, disease is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, Sprycel®, Tasigna®, Bosulif®, Iclusig®) [off-label];
      **Prior authorization may be required for tyrosine kinase inhibitor therapy*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 2.25 mg/m^2 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

B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Marqibo for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 2.25 mg/m^2 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 or evidence of coverage documents;

B. Patients with the demyelinating form of Charcot-Marie-Tooth syndrome.

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: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib (Gleevec®)	600 mg PO QD	600 mg/day
Sprycel (dasatinib)	140 mg PO QD	180 mg/day
Tasigna (nilotinib)	400 mg PO BID	800 mg/day
Bosulif (bosutinib)	400-500 mg PO QD	600 mg/day
Iclusig (ponatinib)	45 mg PO QD	45 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Patients with demyelinating conditions including Charcot-Marie-Tooth syndrome
  - Intrathecal administration
- Boxed warning(s): for intravenous use only – fatal if given by other routes; dosage recommendations differ from vincristine sulfate, verify drug name and dose to avoid overdosage

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

VI. Product Availability

Marqibo Kit containing the following:
- Vial: vincristine sulfate injection, USP 5 mg/5 mL (1 mg/mL)
- Vial: sphingomyelin/cholesterol liposome injection 103 mg/mL
- Vial: sodium phosphate injection 355 mg/25 mL (14.2 mg/mL)

VII. References

1. Marqibo Prescribing Information. Irvine, CA: Spectrum Pharamaceuticals, Inc.; November 2016. Available at: http://www.marqibo.com/pi/. Accessed July 16, 2018.
2. Vincristine sulfate liposome. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed July 16, 2018.
3. Acute lymphoblastic leukemia (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed July 16, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.07.18	11.18

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.