## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

| | |
|---|---|
| **Plan: PA Health & Wellness** | **Submission Date: 11/01/2022** |
| **Policy Number: PA.CP.PHAR.315** | **Effective Date: 01/2018**<br>**Revision Date: 10/2022** |
| **Policy Name: Vincristine Sulfate Liposome Injection (Marqibo)** | |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

4Q 2022 annual review: changed to off-label usage for ALL due to FDA withdrawal but still supported by NCCN; references reviewed and updated.

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Venkateswara R. Davuluri, MD** | **Signature of Authorized Individual:** |

# Clinical Policy: Vincristine Sulfate Liposome Injection (Marqibo)

Reference Number: PA.CP.PHAR.315
Effective Date: 01/2018
Last Review Date: 10/2022

Coding Implications
Revision Log

**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 approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

* On May 2, 2022, the FDA has withdrawn approval of Marqibo after a postmarking clinical trial failed to verify the clinical benefit of the drug. The most updated NCCN guidance (Acute Lymphoblastic Leukemia v1.2022) still supports usage.

**Policy/Criteria**
It is the policy of PA Health & Wellness ® that Marqibo is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Acute Lymphoblastic Leukemia (off-label NCCN recommended use)** (must meet all):

1. Diagnosis of acute lymphoblastic leukemia (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 (*see Appendix B for examples*);
   b. For members with Philadelphia chromosome-positive (Ph+) ALL, disease is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib [Gleevec®], Sprycel®, Tasigna®, Bosulif®, Iclusig®);
   **Prior authorization is (or may be) required*
5. Prescribed as a single agent;
6. 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:** Refer to PA.CP.PMN.53

**II. Continued Approval**

**A. Acute Lymphoblastic Leukemia (off-label NCCN recommended use)** (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 PA Health & 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.PMN.53

**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 policies – PA.CP.PMN.53;

**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 for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Examples of Ph- ALL anti-leukemia therapies** | | |
| • CALGB 8811 Larson regimen: daunorubicin, vincristine, prednisone, pegaspargase, cyclophosphamide<br>• Single agent therapies such as blinatumomab, inotuzumab ozogamicin | Varies | Varies |
| **Ph+ ALL tyrosine kinase inhibitor therapy** | | |
| 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
  - Hypersensitivity to vincristine sulfate or any of the other components of Marqibo (vinCRIStine sulfate LIPOSOME injection)
  - 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

*Appendix D: General Information*

- On May 2, 2022, the FDA withdrew approval of Marqibo after a postmarking clinical trial failed to verify the clinical benefit of the drug. The manufacturer voluntarily withdrew its new drug application and drug approval was subsequently withdrawn.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| ALL (off-label) | 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. East Windsor, NJ: Acrotech Biopharma, LLC; March 2022. Available at: https://marqibo.com . Accessed August 2, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed August 2, 2022.
3. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2022. Available at www.nccn.org. Accessed August 2, 2022.
4. Food and Drug Administration, HHS. Acrotech Biopharm LLC; Withdrawal of approval of new drug application for marqibo (vincristine sulfate liposome injection), 5 miligrams/ 5 milliliters. Fderal Register. May 2, 2022. Available at https://www.federalregister.gov/documents/2022/05/02/2022-09235/acrotech-biopharma-llc-withdrawal-of-approval-of-new-drug-application-for-marqibo-vincristine. Accessed August 2, 2022.

## 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 | Approval Date |
|---|---|---|
| 4Q 2018 annual review: no significant changes; added prescriber restrictions; references reviewed and updated. | 07/2018 | |
| 4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020 | 10/2019 | |
| 4Q 2020 annual review Ph- anti-leukemia therapy examples added to Appendix B; FDA/NCCN dosing limitation added; references reviewed and updated. | 10/2020 | |
| 4Q 2021 annual review: added requirement for use as a single agent per NCCN and pivotal trial; updated Appendix C to include hypersensitivity contraindication; references reviewed and updated. | 10/2021 | |
| 4Q 2022 annual review: changed to off-label usage for ALL due to FDA withdrawal but still supported by NCCN; references reviewed and updated. | 10/2022 | |