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5.21.42

Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 13, 2013
Subject:	Marqibo	**Page:**	1 of 4

Last Review Date: June 16, 2022

Marqibo

Description

Marqibo (vincristine liposome injection)

Background
Marqibo (vincristine) is used for the treatment of adults with Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL). Marqibo is approved for patients whose leukemia has relapsed two or more times, or whose leukemia has progressed following two or more regimens of anti-leukemia therapy. Marqibo contains vincristine, which is a chemical that stops cancer cells from dividing. The vincristine is encased within a liposome, a drug delivery vehicle composed of material similar to that of cell membranes, which delivers the drug direct to cancer cells (1).

Regulatory Status
FDA-approved indication: Marqibo is a vinca alkaloid 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 (1).

Marqibo has a boxed warning that the drug must only be given intravenously. Death has occurred with intrathecal use. Patients must be monitored for neurologic and myelosuppression symptoms such as neuropathy, neutropenia, thrombocytopenia, and anemia. Marqibo is contraindicated in patients with demyelinating conditions including Charcot-Marie-Tooth syndrome (1).

The safety and effectiveness of Marqibo has not been established in pediatric patients (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Marqibo may be considered **medically necessary** in patients that are 18 years of age and older with acute lymphoblastic leukemia (ALL) and if the conditions indicated below are met.

Marqibo may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have **ALL** of the following:

1. Acute lymphoblastic leukemia (ALL)
    a. Philadelphia chromosome-negative (Ph-)
    b. Two or more relapses or disease progression following two or more anti-leukemia therapies

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have **ALL** of the following:

1. Acute lymphoblastic leukemia (ALL)
    a. Philadelphia chromosome-negative (Ph-)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Marqibo is a new liposome-encapsulated formulation of vincristine sulfate. It is indicated for patients 18 years of age and older with Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (ALL). Marqibo is contraindicated in demyelinating conditions including Charcot-Marie-Tooth syndrome (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Marqibo while maintaining optimal therapeutic outcomes.

References

1. Marqibo [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; June 2020.
2. NCCN Drugs & Biologics Compendium® Vincristine 2022. National Comprehensive Cancer Network, Inc. Accessed on April 25, 2022.

Policy History

Date	Action/Reason
December 2012	Addition to PA
March 2013	PMPC Review
September 2014	Annual criteria review and reference update
March 2015	Annual criteria review and reference update
June 2016	Annual editorial review and reference update Policy code changed from 5.04.42 to 5.21.42

June 2017	Annual editorial review and reference update Addition of age limits to renewal criteria
June 2018	Annual editorial review and reference update
June 2019	Annual review
June 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.