Reference number(s)
4815-A

STANDARD MEDICARE PART B MANAGEMENT

MARQIBO (vincristine sulfate liposome injection)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

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.

B. Compendial Uses

Acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LL) as single-agent therapy for relapsed/refractory:

1. Philadelphia chromosome-negative B-ALL/LL or T-ALL/LL
2. Philadelphia chromosome-positive B-ALL/LL refractory to tyrosine kinase inhibitors (TKIs)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

Coverage will not be provided for members with demyelinating conditions including Charcot-Marie-Tooth syndrome.

III. CRITERIA FOR INITIAL APPROVAL

Acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LL)
Authorization of 12 months may be granted for treatment of relapsed or refractory ALL/LL when either of the following criteria is met:

A. The member has Philadelphia chromosome-negative ALL/LL.
B. The member has Philadelphia chromosome-positive ALL/LL that is refractory to a tyrosine kinase inhibitor (TKI) therapy.

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IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with Marqibo
B. Marqibo is being used to treat an indication enumerated in Section III
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen AND
    2. No evidence of disease progression while on the current regimen

V. REFERENCES

1. Marqibo [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; June 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 2, 2021.
3. NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2021). © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 6, 2021.