

Medical Policy:

Marqibo® (vincristine sulfate liposomal) Intravenous

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|----------------|-------------|
| MG.MM.PH.49 | March 18, 2025 | |

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Marqibo (vincristine sulfate liposomal) 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.

Marqibo (vincristine sulfate liposomal) 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. The drug is for intravenous use only. Marqibo is contraindicated for intrathecal administration.

Marqibo (vincristine sulfate liposomal) has different dosage recommendations than vincristine sulfate injection. Drug name and dose must be verified prior to preparation and administration to avoid over dosage.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 40 billable units every 28 days

Guideline

Marqibo (vincristine sulfate liposomal) is considered medically necessary for the following diagnosis when all-of the following criteria are met:

1. Relapsed or progressed Acute Lymphoblastic Leukemia (ALL)

- A. Patient is at least 18 years old; **AND**
- B. Used for relapsed or refractory disease
- C. Patient's disease is Philadelphia chromosome-negative (Ph-); **OR**
- D. Patient has Philadelphia chromosome-positive (Ph+) B-ALL and is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, ponatinib, etc.); **AND**
- E. Patient does not have any pre-existing demyelinating conditions (e.g. Charcot-Marie-Tooth Syndrome); **AND**
- F. Marqibo is being used as single agent therapy.

Coverage for Marqibo (vincristine sulfate liposomal) may be renewed when the following criteria are met:

1. Stabilization and/or absence of progression of disease; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: peripheral motor and sensory, central and autonomic neuropathy; myelosuppression; neutropenia; thrombocytopenia; anemia; tumor lysis syndrome; elevated liver function tests (ALT, AST, and bilirubin).

Limitations/Exclusions

Approval will be granted for six months and may be renewed.

Applicable Procedure Codes

| Code | Description |
|-------|---|
| J9371 | Injection, vincristine sulfate liposome, 1 mg; 1 mg = 1 billable unit |

Applicable NDCs

| Code | Description |
|---------------|-----------------------------|
| 72893-0008-03 | Marqibo 5mg/31mL Suspension |

ICD-10 Diagnoses

| Code | Description |
|--------|--|
| C91.02 | Acute lymphoblastic leukemia, in relapse |

Revision History

| Company(ies) | DATE | REVISION |
|--------------|------|----------|
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|-----------------------------|------------|---|
| EmblemHealth & ConnectiCare | 03/18/2025 | Annual Review: updated ICD-10 codes, no criteria changes. |
| EmblemHealth & ConnectiCare | 2/2/2024 | Annual Review: no criteria changes |
| EmblemHealth & ConnectiCare | 6/5/2023 | Annual Review: <u>ALL</u> - Initial Criteria, removed: "Patient's disease is in second or greater relapse; OR Patient's disease has progressed following two or more anti-leukemia therapies; AND" added "Used for relapsed or refractory disease, Patient has Philadelphia chromosome-positive (Ph+) B-ALL and is refractory to tyrosine kinase inhibitor therapy (e.g., imatinib, dasatinib, nilotinib, ponatinib, etc.); AND" Removed NDC: 20536-0322-01 |
| EmblemHealth & ConnectiCare | 09/07/2022 | Transferred policy to new template |
| EmblemHealth & ConnectiCare | 12/30/2020 | Annual review |

References

1. Marqibo [package insert]. San South San Francisco, CA: Talon Therapeutics; June 2020. Accessed December 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for vincristine sulfate liposomal. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2020.