I. Medication Description

Vincristine sulfate liposomes injection (Marqibo®) is a novel formulation that encapsulates vincristine in proprietary liposome nano-particles called Optisomes™. Optisomes are made from sphingomyelin and cholesterol, which are normal components of human plasma membranes. Optisomes are uniquely suited to contain, deliver, and dose-intensify vincristine. Marqibo® has longer plasma circulation time than vincristine, targets encapsulated drug preferentially to tumors, and delivers vincristine to tumor cells in a continuous and prolonged manner, maximizing its cell cycle dependent activity on malignant cells. 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.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided when the following criteria are met:

- Member is 18 years of age or older AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for a quantity sufficient to allow for FDA-approved dosing (2.25 mg/m² weekly).

V. Coverage Duration

Coverage is granted for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- J9371, 1 billable unit = 1mg
- 5mg single-use vials
- Pertinent indication:
  - Acute Lymphoblastic Leukemia: C91.00 – C91.02

VIII. Summary of Policy Changes

- 12/15/12: new policy
- 1/1/14: J code introduced
- 3/15/14: requires oncologist prescriber
- 3/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 9/15/15: no policy changes
- 7/19/16: policy updated to correspond with current NCCN treatment guidelines
- 3/21/17: updated coverage criteria to allow use supported by NCCN guidelines
- 6/15/18: no policy changes

IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.