CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Other) – Valrubicin Products Utilization Management Medical Policy
- Valstar® (valrubicin intravesical solution– Endo, generic)

REVIEW DATE: 12/18/2024

OVERVIEW
Valrubicin, an anthracycline topoisomerase inhibitor, is indicated for intravesical therapy of BCG-refractory **carcinoma *in situ* (CIS) of the urinary bladder** in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.[1]

Guidelines
The National Comprehensive Cancer Network guidelines for **bladder cancer** (version 5.2024 – October 28, 2024) recommend intravesical valrubicin in the event of a Bacillus Calmette-Guerin (BCG) shortage and for BCG-refractory carcinoma *in situ* (Tis) disease as either initial therapy if high risk and BCG unresponsive or intolerant, or for recurrent or persistent disease.[2,3]

Dosing
The recommended dose of valrubicin is 800 mg administered intravesically once a week for 6 weeks.[1]

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of valrubicin. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with valrubicin as well as the monitoring required for adverse events and long-term efficacy, approval requires valrubicin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of valrubicin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Bladder Cancer. Approve for 2 months if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i, ii, or iii):
  - **i.** Patient has Bacillus Calmette-Guerin (BCG)-refractory carcinoma; OR
  - **ii.** Patient is intolerant of Bacillus Calmette-Guerin (BCG); OR

iii. According to the prescriber, valrubicin will be used due to a Bacillus Calmette-Guerin (BCG) shortage; AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Each individual dose must not exceed 800 mg administered intravesically no more frequently than once weekly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of valrubicin is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Valstar solution [prescribing information]. Malvern, PA: Endo Pharmaceuticals Solutions; October 2019.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 17, 2024. Search term: valrubicin.
3. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – October 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 17, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023
Annual Revision	No criteria changes.	12/18/2024