

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Intravesical) – Valrubicin Products Utilization Management Medical Policy

- Valstar® (valrubicin intravesical solution – Endo, generic)

REVIEW DATE: 12/10/2025

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 2.2025 – October 10, 2025) recommend intravesical valrubicin in the event of a Bacillus Calmette-Guerin (BCG) shortage as initial or adjuvant therapy for intermediate or high risk non-muscle invasive bladder cancer (category 2A).^{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. Non-Muscle Invasive 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

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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. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2025. Search term: valrubicin.
3. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – October 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2025.

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
Update	04/04/2025: The policy name was changed from “Oncology (Other) – Valrubicin Products UM Medical Policy” to “Oncology (Intravesical) – Valrubicin Products UM Medical Policy”.	N/A
Annual Revision	Non-Muscle Invasive Bladder Cancer: This indication was changed to as listed (previously was Bladder Cancer).	12/10/2025