

## Clinical Policy: Valrubicin (Valstar)

Reference Number: PA.CP.PHAR.439

Effective Date: 01/2020

Last Review Date: 10/2025

### Description

Valrubicin (Valstar<sup>®</sup>) is an anthracycline topoisomerase inhibitor.

### FDA Approved Indication(s)

Valstar is indicated for the intravesical therapy of bacillus Calmette-Guerin (BCG)-refractory carcinoma *in situ* (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness<sup>®</sup> that Valstar and valrubicin are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Bladder Cancer (must meet all):

1. Diagnosis of CIS of the urinary bladder;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age  $\geq$  18 years;
4. One of the following (a or b)\*:
  - a. Member is refractory to BCG treatment and is not a candidate for cystectomy;
  - b. prescribed as initial management or as adjuvant intravesical chemotherapy for non-muscle invasive bladder cancer (NMIBC) in the event of a BCG shortage (*see Appendix D for information on BCG shortage*);
5. For brand Valstar requests, member must use generic valrubicin, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
  - a. Dose does not exceed 800 mg per week for a total of 6 doses;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prior authorization may be required for BCG immunotherapy*

**Approval duration: 6 weeks (6 doses)**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**II. Continued Therapy**

**A. Bladder Cancer (must meet all):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Member has not yet received a total of 6 doses;
4. For brand Valstar requests, member must use generic valrubicin, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, request meets one of the following (a or b):
  - a. New dose does not exceed 800 mg per week up to a total of 6 doses;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: Up to a total of 6 weeks (up to a total of 6 doses)**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53**

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

AUA: American Urological Association  
BCG: bacillus Calmette-Guerin  
CIS: carcinoma *in situ*

FDA: Food and Drug Administration  
NMIBC: non-muscle-invasive bladder cancer

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Bacillus Calmette-Guerin live (TICE BCG®)	1 to 8 × 10 <sup>8</sup> CFU (a vial) intravesical instillation once per week for 6 weeks	1 to 8 × 10 <sup>8</sup> CFU/week

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s):
  - Perforated bladder or compromised bladder mucosa
  - Known hypersensitivity to anthracyclines or polyoxyl castor oil
  - Concurrent urinary tract infections
  - Small bladder capacity, i.e., unable to tolerate a 75 mL instillation
- Boxed warning(s): none reported

*Appendix D: General Information*

- Carcinoma *in situ* (Tis in TNM staging system) refers to early cancer that has not spread to neighboring tissue.
- Centers for Disease Control’s current shortages page: <https://www.fda.gov/vaccines-blood-biologics/safetyavailability-biologics/cber-regulated-products-current-shortages>
- National Comprehensive Cancer Network (NCCN) and American Urological Association (AUA) information and recommendations:
  - Standard urinary bladder CIS therapy includes lesion resection followed by intravesical BCG.
- The NCCN and AUA advises that in the event of BCG shortage, BCG should be prioritized for induction of high-risk patients (e.g., high-grade T1 and CIS) and that, if feasible, the dose of BCG may be split (1/3 or 1/2 dose) so that multiple patients may be treated with a single vial in the event of a shortage.
  - If BCG is unavailable, the NCCN and AUA recommends the following alternatives:
    - Intravesical chemotherapy agents as first-line and subsequent therapy (e.g., gemcitabine, mitomycin, epirubicin, valrubicin, docetaxel, sequential gemcitabine/docetaxel, gemcitabine/mitomycin);
    - Initial radical cystectomy if patient is a surgical candidate.

1. National Comprehensive Cancer Network Guidelines. Bladder Cancer Version 3.2024. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf). Accessed July 22, 2025.

2. American Urological Association. BCG Shortage Info. Feb 2019. Available at: <https://www.auanet.org/about-us/bcg-shortage-info>. Accessed July 22, 2025.

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Bladder CIS	800 mg intravesically once every week for 6 weeks	800 mg/dose

**VI. Product Availability**

Single-use vial: 200 mg/5 mL

**VII. References**

1. Valrubicin Prescribing Information. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; June 2022. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8739ae02-e4c5-0fa2-e053-2a91aa0a1b74>. Accessed July 22, 2025.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed July 22, 2025.
3. Quan Y, Jeong CW, Kwak C, et al. Dose, duration, and strain of bacillus Calmette-Guerin in the treatment of nonmuscle invasive bladder cancer. *Medicine (Baltimore)*. 2017; 96(2):e8300.
4. National Comprehensive Cancer Network. Bladder Cancer Version 1.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf). Accessed July 22, 2025.
5. American Urological Association: Important message about the BCG shortage: <https://www.auanet.org/about-us/bcg-shortage-info>. Accessed July 22, 2025.
6. Holzbeierlein J, Bixler BR, Buckley DI, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. *J Urol*. 2024;10.1097/JU.0000000000003846.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9357	Injection, valrubicin, intravesical, 200 mg

Reviews, Revisions, and Approvals	Date
New Policy Created	01/2020
4Q 2020 annual review: revised criteria to include adjuvant intravesical chemotherapy for non-muscle invasive bladder cancer in the event of a BCG shortage as per NCCN 2A or above off label indication; updated Appendix D with information on BCG shortage; references reviewed and updated.	08/2020
4Q 2021 annual review: clarified in initial approval that request not exceed a total of 6 doses in accordance with authorization duration; references reviewed and updated.	10/2021
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022
4Q 2023 annual review: no significant changes; references reviewed and updated.	10/2023
4Q 2024 annual review: clarified that policy applies to generic valrubicin; added criterion for brand Valstar requests, that member must use generic valrubicin; references reviewed and updated.	10/2024
4Q 2025 annual review: added option of urologist to fulfill specialist requirement; removed specification of recurrent or persistent disease and added option for use as initial intravesical chemotherapy for NMIBC per NCCN; clarified failure of BCG to member is refractory to BCG treatment and added criterion that member is not a candidate for cystectomy per FDA labeling; references reviewed and updated.	10/2025