Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2021**
Policy Number: PA.CP.PHAR.439	**Effective Date: 01/2020** **Revision Date: 10/2021**
Policy Name: Valrubicin (Valstar)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

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.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Valrubicin (Valstar)

Reference Number: PA.CP.PHAR.439
Effective Date: 01/2020
Last Review Date: 10/2021

Revision Log

Description
Valrubicin (Valstar®) is an anthracycline.

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 health plans affiliated with PA Health & Wellness® that Valstar is **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;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b)*:
   a. Failure of intravesical BCG treatment, unless contraindicated or clinically significant adverse effects are experienced;
   b. 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*);

   **Prior authorization may be required for BCG immunotherapy*
5. 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*).

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.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Member has not yet received a total of 6 doses;
4. 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;
   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.LTSS.PHAR.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
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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
BCG	81 mg intravesically once a week for 6 weeks	Undetermined

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.
- The American Urological Association (AUA) recommends several management approaches to maintain high quality care for patients with non-muscle-invasive bladder cancer (NMIBC). As always, these recommendations are subject to physician judgment in individual cases:
  - BCG should not be used for patients with low-risk disease.
  - Intravesical chemotherapy should be used as the first-line option for patients with intermediate-risk NMIBC. Patients with recurrent/multifocal low-grade Ta lesions who require intravesical therapy should receive intravesical chemotherapy such as mitomycin, gemcitabine, epirubicin, or docetaxel instead of BCG.
  - If BCG would be administered as second-line therapy for patients with intermediate-risk NMIBC, an alternative intravesical chemotherapy should be used rather than BCG in the setting of this BCG shortage.
  - For patients with high-risk NMIBC, high-grade T1 and CIS patients receiving induction therapy, they should be prioritized for use of full-strength BCG. If not available, these patients and other high-risk patients may be given a reduced 1/2 to 1/3 dose, if feasible.
  - If supply exists for maintenance therapy for patients with NMIBC, limit BCG dose to one year.
  - In the event of BCG supply shortage, maintenance therapy should not be given and BCG naïve patients with high-risk disease should be prioritized for induction BCG.
  - If BCG is not available, alternatives to BCG such as gemcitabine, epirubicin, docetaxel, valrubicin, mitomycin, or sequential gemcitabine/docetaxel or gemcitabine/mitomycin may also be considered with an induction and possible maintenance regimen.
  - Patients with high-risk features (i.e., high-grade T1 with additional risk factors such as concomitant CIS, lymphovascular invasion, prostatic urethral involvement or variant histology) who are not willing to take any potential oncologic risks with alternative intravesical agents, should be offered initial radical cystectomy, if they are surgical candidates.
- The NCCN guidance in the event of a BCG shortage is generally in accordance with AUA stance. They advise BCG should be prioritized for induction of high-risk patients NMIBC (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 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 4.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed August 9, 2021.
2.American Urological Assoication. BCG Shortage Info. Feb 2019. Available at: https://www.auanet.org/about-us/bcg-shortage-info. Accessed August 9, 2021.

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 vials: 200 mg/5 mL

VII. References

1. Valstar Prescribing Information. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; October 2019. Available at: http://valstarsolution.com/patient/. Accessed August 5, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 5, 2021.
3. Quan Y, Jeong CW, Kwak C, et al. Dose, duration, and strain of bacillus Calmette-Guerin in the treatment of nonmuscule invasive bladder cancer. Medicine (Baltimore). 2017; 96(2):e8300. doi: 10.1097/MD.0000000000008300.
4. National Comprehensive Cancer Network. Bladder Cancer Version 4.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed August 5, 2021.
5. American Urological Association: Important message about the BCG shortage: https://www.auanet.org/about-us/bcg-shortage-info. Accessed August 5, 2021.

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	P&T Approval 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	11/2020

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	