

**Clinical Policy: Valrubicin (Valstar)****Reference Number: LA.PHAR.439****Effective Date:****Last Review Date: 01.21****Line of Business: Medicaid****[Revision Log](#)**

**See [Important Reminder](#) at the end of this policy for important regulatory and legal information.**

**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**

***Prior authorization is required. 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 Louisiana Healthcare Connections that Valstar is medically necessary when the following criteria are met:**

**I. Initial Approval Criteria****A. Bladder Cancer (must meet all):**

- 1. Diagnosis of recurrent or persistent 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. Adjuvant intravesical chemotherapy for non-muscle invasive bladder cancer in the event of a BCG shortage (see Appendix D for information on BCG shortage);**
- 5. Request meets one of the following (a or b):\***
  - a. Dose does not exceed 800 mg per week;**
  - 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**

**\*Prescribed regimen must be FDA-approved or recommended by NCCN**

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

**B. Other diagnoses/indications**

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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): LA.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Valstar for a covered indication and has received this medication for at least 30 days;
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).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

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 Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.  
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): LA.PMN.53 for Medicaid.

**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 –LA.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

Appendix A: Abbreviation/Acronym Key

BCG: bacillus Calmette-Guerin

CIS: carcinoma in situ

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/ Maximum Dose</u>
<u>BCG</u>	<u>81 mg intravesically one a week for 6 weeks, followed by a rest period of 4 to 6 weeks, with a full re-evaluation at week 12 after the start of therapy</u>	<u>Undetermined</u>

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):**
  - **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 advises 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, a preferable alternative to BCG is mitomycin (induction and monthly maintenance up to one year). Other options such as gemcitabine, epirubicin, docetaxel, valrubicin 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 carcinoma in situ, 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 advises that in the event of a 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 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 6.2020. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf). Accessed August 17, 2020.

2. American Urological Association. BCG Shortage Info. Feb 2019. Available at: <https://www.auanet.org/about-us/bcg-shortage-info>. Accessed August 17, 2020.

**V. Dosage and Administration**

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

**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 3, 2020.
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 August 3, 2020.
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. doi: [10.1097/MD.00000000000008300](https://doi.org/10.1097/MD.00000000000008300).
4. National Comprehensive Cancer Network. Bladder Cancer Version 5.2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf). Accessed August 3, 2020.
5. American Urological Association: Important message about the BCG shortage; <https://www.auanet.org/about-us/bcg-shortage-info>

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy.	<u>1/7/2021</u>

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**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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~~Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.~~

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