

Clinical Policy: Valrubicin (Valstar)

Reference Number: CP.PHAR.439

Effective Date: 09.04.18

Last Review Date: 11.20

Line of Business: Medicaid, HIM

[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

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 Centene Corporation[®] 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 \geq 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

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Bladder Cancer (must meet all):

1. Currently receiving medication via Centene 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 Centene 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.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 – HIM.PHAR.21 for health insurance marketplace and CP.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 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 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	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):
 - 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. 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

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 3, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: 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. Accessed August 3, 2020.
5. American Urological Association: Important message about the BCG shortage: <https://www.auanet.org/about-us/bcg-shortage-info>

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.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy HIM.PA.10 (to be retired); added HIM and Medicaid lines of business; no significant changes; references reviewed and updated.	08.13.19	11.19
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; added HCPSC codes; updated Appendix D with information on BCG shortage; references reviewed and updated.	10.20.20	11.20

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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

©2018 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or

remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.