RXADVANCE
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Clinical Policy Title:	valrubicin
Policy Number:	RxA.536
Drug(s) Applied:	Valstar®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Valrubicin (Valstar®) is an anthracycline. It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
valrubicin (Valstar®)	Bladder CIS	800 mg intravesically once weekly for 6 weeks	800 mg/dose

Dosage Forms

- Single-use vials: 200 mg/5 mL

Clinical Policy

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

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. Failure of intravesical BCG treatment, unless contraindicated or clinically significant adverse effects are experienced;
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*).

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

Approval Duration

Commercial: 42 days (6 doses)

Medicaid: 42 days (6 doses)

II. Continued Therapy Approval

A. Bladder Cancer (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy 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

Commercial: Up to a total of 42 days (up to a total of 6 doses)

Medicaid: Up to a total of 42 days (up to a total of 6 doses)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

BCG: bacillus Calmette-Guerin
CIS: carcinoma *in situ*
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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 neighbouring

tissue.

References

1. Valstar Prescribing Information. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; Oct 2019. Available at: http://valstarsolution.com/patient/. Accessed September 7, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed September 7, 2020.
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 6.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed September 7, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Line of business policy applies was updated to All lines of business. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. References were updated.	9/7/2020	12/07/2020