POLICY: Oncology – Valrubicin solution for intravesical use (Valstar – Endo Pharmaceuticals Solution, generics)

APPROVAL DATE: 10/16/2019

OVERVIEW

Valrubicin (Valstar), an anthracycline topoisomerase inhibitor, is indicated for intravesical therapy of BCG-refractory carcinoma *in situ* (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.[1]

Guidelines

The National Comprehensive Cancer Network guidelines for bladder cancer (Version 4.2019 – July 10, 2019) recommend intravesical valrubicin in the event of a Bacillus Calmette-Guerin (BCG) shortage and for recurrent or persistent BCG-refractory carcinoma *in situ* (Tis) disease.[2,3]

Dosing

The recommended dose of valrubicin is 800 mg administered intravesically once a week for 6 weeks.[1]

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of valrubicin. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Because of the specialized skills required for evaluation and diagnosis of patients treated with valrubicin as well as the monitoring required for adverse events and long-term efficacy, approval requires valrubicin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of valrubicin is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Bladder Cancer.** Approve for 2 months if the patient meets the following criteria (A, B, and C):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient meets one of the following (i or ii):
     - **i.** The patient has recurrent or persistent Bacillus Calmette-Guerin (BCG)-refractory carcinoma; OR
     - **ii.** According to the prescriber, valrubicin will be used due to a Bacillus Calmette-Guerin (BCG) shortage; AND
   - **C)** Valrubicin is prescribed by or in consultation with an oncologist.

Dosing. Each individual dose must not exceed 800 mg administered intravesically no more frequently than once weekly.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Valrubicin has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Valstar solution [prescribing information]. Malvern, PA: Endo Pharmaceuticals Solutions; April 2016.
2. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 25, 2019. Search term: valrubicin.
3. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 4.2019 – July 10, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 25, 2019.

HISTORY

Type of Revision	Summary of Changes	Approval Date
New Policy	--	10/16/2019