

Drug Policy:

Valstar™ (valrubicin)

POLICY NUMBER UM ONC_1070	SUBJECT Valstar™ (valrubicin)	DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 02/20/11, 05/09/12, 02/12/14, 12/12/15, 08/23/16, 08/10/17, 08/08/18, 07/10/19, 12/11/19, 07/08/20, 07/14/21, 11/15/21, 05/11/22, 06/08/22, 08/09/23, 08/14/24	APPROVAL DATE August 14, 2024	EFFECTIVE DATE August 30, 2024	COMMITTEE APPROVAL DATES 02/20/11, 05/09/12, 02/12/14, 12/12/15, 08/23/16, 08/10/17, 08/08/18, 07/10/19, 12/11/19, 07/08/20, 07/14/21, 11/15/21, 05/11/22, 06/08/22, 08/09/23, 08/14/24
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Valstar (valrubicin) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication **AND**
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization **AND**
3. Additional medication(s) are not being added to the continuation request.

B. Non-Muscle Invasive Bladder Cancer (Tis-Carcinoma In Situ)

1. The member has recurrent or persistent non-muscle invasive carcinoma of the bladder-Tis or Carcinoma In Situ-that is refractory/intolerant to local (intravesical) therapy with BCG. Refractory is defined as a loss of response to treatment within 6 months of induction or 12 months of maintenance with at least the first course of induction (5-6 doses) followed by maintenance/second induction (of at least 2 doses) of BCG treatment.

III. EXCLUSION CRITERIA

- A. The member has an active urinary tract infection (UTI).
- B. Dosing exceeds single dose limit of Valstar (valrubicin) 800 mg.
- C. Total induction doses of Valstar (valrubicin) exceed 2 cycles (or 12 doses).
- D. Total maintenance doses of Valstar (valrubicin) exceed 10 cycles (or 10 doses).
- E. Investigational use of Valstar (valrubicin) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
 - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
 - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
 - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 - 4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
 - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
 - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
 - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Steinberg RL, et al., 2016, Bacillus Calmette-Guérin (BCG) Treatment Failures with Non-Muscle Invasive Bladder Cancer: A Data-Driven Definition of BCG Unresponsive Disease, Bladder Cancer, 2:215–224.
- B. Clinical Pharmacology Elsevier Gold Standard 2024.



- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2024
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.
- E. Valstar prescribing information. Endo Pharmaceuticals Solutions Inc. Malvern, PA 2021.
- F. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.
- G. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services:
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- H. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA:
<http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

