Evolent Clinical Guideline 3026 for Yondelis™ (trabectedin)

Guideline Number:	Applicable Codes	
Evolent_CG_3026		
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Original Date:	**Last Revised Date:**	**Implementation Date:**
April 2016	February 2025	February 2025

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STATEMENT

Purpose

To define and describe the accepted indications for Yondelis (trabectedin) 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.

INDICATIONS

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

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

Soft Tissue Sarcoma

- The member has unresectable or metastatic soft tissue sarcoma (Leiomyosarcoma, liposarcoma, and translocation-related sarcomas) AND Yondelis (trabectedin) may be used as monotherapy or in combination with doxorubicin as first line or subsequent therapy.
- NOTE: Yondelis (trabectedin) is not supported by Evolent Policy for the treatment of other soft tissue sarcoma histologies that are not leiomyosarcoma, liposarcoma, and translocation-related sarcomas. This policy position is based on the T-SAR trial which demonstrated no clinically meaningful improvement in overall survival or progression free survival with Yondelis (trabectedin) when compared to best supportive care for patients with advanced translocation-related sarcoma. Please refer to the alternative agents/regimens recommended by Evolent, including but not limited to regimens available at **Evolent Pathways**

Uterine Sarcoma

- The member has unresectable or metastatic uterine leiomyosarcoma AND
- Yondelis (trabectedin) is being used as single agent for members with disease progression with prior anthracycline-based chemotherapy unless there is a contraindication/intolerance with prior anthracycline based therapy.

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - Known hypersensitivity to Yondelis (trabectedin)

EXCLUSION CRITERIA

- Disease progression while on Yondelis (trabectedin).
- Dosing exceeds single dose limit of Yondelis (trabectedin) 1.5 mg/m^2.
- Investigational use of Yondelis (trabectedin) 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:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions 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.
  - Whether the experimental design, considering 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).
  - 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.
  - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - 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.

CODING AND STANDARDS

Codes

- J9352 - Injection, trabectedin, 0.1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
February 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1290 Yondelis (trabectedin)
February 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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