CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Trabectedin Products Utilization Management Medical Policy
- Evdi (trabectedin intravenous infusion – Apotex)
- Yondelis® (trabectedin intravenous infusion – Janssen)

REVIEW DATE: 06/17/2026

OVERVIEW

Trabectedin, an alkylating agent, is indicated for the treatment of patients with unresectable or metastatic **liposarcoma or leiomyosarcoma** in adults who received a prior anthracycline-containing regimen.[1]

Guidelines

Trabectedin is addressed in the following National Comprehensive Cancer Network (NCCN) guidelines:

- **Soft Tissue Sarcoma** (version 3.2026 – March 12, 2026) clinical practice guidelines recommend trabectedin for the following indications:[2,3]
  - Dedifferentiated Liposarcoma with or without concurrent Well-Differentiated Liposarcoma – as a single agent under "Other Recommended" regimen (category 2A).
  - Extremity/Body Wall, Head/Neck – as a single agent for neoadjuvant/adjuvant, or palliative therapy; and in combination with doxorubicin for first-line treatment;
  - Retroperitoneal/Intra-abdominal – as a single agent for neoadjuvant/adjuvant, or palliative therapy; and in combination with doxorubicin for first-line treatment;
  - Rhabdomyosarcoma – as a single agent for palliative therapy;
  - Solitary fibrous tumor – as a single agent for palliative therapy.
- **Uterine Neoplasms** (version 2.2026 – November 14, 2025) clinical practice guidelines recommend trabectedin in combination with doxorubicin as a "Preferred" regimen (category 2A) for the first-line treatment of advanced, recurrent, metastatic, or inoperable leiomyosarcoma.[2,4] Trabectedin is also recommended as a single-agent for the treatment of leiomyosarcoma (category 2A) that has been treated previously with an anthracycline-containing regimen for disease that is not suitable for primary surgery, a radiologically isolated vaginal/pelvic recurrence, unresectable isolated metastases or disseminated disease, or postoperatively for resectable isolated metastases.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of trabectedin. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. 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. Because of the specialized skills required for evaluation and diagnosis of patients treated with trabectedin as well as the monitoring required for adverse events and long-term efficacy, approval requires trabectedin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   Note: This includes borderline/malignant phyllodes tumor of the breast, dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma, epithelioid hemangioendothelioma, extremity/body wall, head/neck, retroperitoneal/intra-abdominal, rhabdomyosarcoma, and solitary fibrous tumor.
   A) Patient is ≥ 2 years of age; AND
   B) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 1.5 mg/m^2 administered by intravenous infusion a maximum of once in each 21-day cycle.

2. **Uterine Leiomyosarcoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has advanced, recurrent, metastatic, or inoperable disease; AND
   C) The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 1.5 mg/m^2 administered by intravenous infusion a maximum of once in each 21-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of trabectedin is not recommended in the following situations:

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. Yondelis® intravenous infusion [prescribing information]. Horsham, PA: Janssen; December 2025.
2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 4, 2026. Search term: trabectedin.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 3.2026 – March 12, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 4, 2026.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2026 – November 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 4, 2026.
5. Evdi® intravenous infusion [prescribing information]. Weston, FL: Apotex; May 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	02/05/2025
Annual Revision	**Soft Tissue Sarcoma**: In the Note with sarcoma subtypes, added borderline/malignant phyllodes tumor of the breast, dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma, and epithelioid hemangioendothelioma.	02/25/2026
Early Annual Revision	The policy name was changed from "Oncology (Injectable) – Yondelis UM Medical Policy" to "Oncology (Injectable) – Trabectedin Products UM Medical Policy". Evdi (trabectedin intravenous infusion) was added to the Policy.	06/17/2026