Utilization Review Policy 266

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

EFFECTIVE DATE: 1/1/2022
REVIEW DATE: 02/05/2025

COVERAGE CRITERIA FOR: All UCare Plans

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

Guidelines
Yondelis is addressed in the following National Comprehensive Cancer Network (NCCN) guidelines:
- **Soft Tissue Sarcoma** (version 4.2024 – November 21, 2024) clinical practice guidelines recommend Yondelis for the following indications:[2,3]
  - 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 1.2025 – December 16, 2024) clinical practice guidelines recommend Yondelis in combination with doxorubicin for the first-line treatment of advanced, recurrent, metastatic, or inoperable leiomyosarcoma.[2,4] Yondelis is also recommended as a single-agent for the treatment of leiomyosarcoma 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 Yondelis. 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 Yondelis as well as the monitoring required for adverse events and long-term efficacy, approval requires Yondelis to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Yondelis 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 Extremity/Body Wall, Head/Neck; Retroperitoneal/Intra-Abdominal; Rhabdomyosarcoma; and Solitary Fibrous Tumors.
A) Patient is ≥ 2 years of age; AND
B) Yondelis 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) Yondelis 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 Yondelis 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; June 2020.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 27, 2025. Search term: trabectedin.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 4.2024 – November 21, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 27, 2025.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2025 – December 16, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 27, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Soft Tissue Sarcoma:** Removed angiosarcoma from the Note. **Uterine Leiomyosarcoma:** Requirement that the patient had received prior anthracycline containing regimen was removed. Removed "unresectable" and added "advanced, recurrent, or inoperable" to requirement that the patient has metastatic disease.	01/18/2023
Annual Revision	**Soft Tissue Sarcoma:** Removed requirement that Yondelis is used as a single agent.	01/17/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	02/05/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025