VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 01/18/2023

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 2.2022 – May 17, 2022) clinical practice guidelines recommend Yondelis as single-agent therapy for the following indications:
  - Extremity/Body Wall, Head/Neck – as neoadjuvant/adjuvant, or palliative therapy;
  - Retroperitoneal/Intra-abdominal – as neoadjuvant/adjuvant, or palliative therapy;
  - Rhabdomyosarcoma – as palliative therapy;
  - Solitary fibrous tumor – as palliative therapy.[2,3]
- **Uterine Neoplasms** (version 1.2023 – December 22, 2022) 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.[2,4]

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

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1. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   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 used as single-agent treatment; 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.

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2. Uterine Leiomyosarcoma. Approve for 1 year if the patient meets the following criteria (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. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 10, 2023. Search term: trabectedin.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 10, 2023.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 10, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Soft Tissue Sarcoma:** Added requirement that the patient is ≥ 2 years of age. **Uterine Leiomyosarcoma:** Added requirement that the patient is ≥ 18 years of age.	12/22/2021
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