



**POLICY:** Oncology – Yondelis® (trabectedin injection for intravenous use – Janssen)

**DATE REVIEWED:** 12/11/2019

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## 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.<sup>1</sup>

## Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on Soft Tissue Sarcoma (Version 4.2019 – September 12, 2019) recommends Yondelis as single-agent palliative therapy for the following:

- Extremity/Superficial Trunk, Head/Neck – synchronous stage IV or recurrent disease with disseminated metastases;
- Retroperitoneal/Intra-abdominal – unresectable or progressive disease;
- Angiosarcoma;
- Rhabdomyosarcoma.<sup>2,3</sup>

The NCCN guidelines on Uterine Neoplasms (Version 4.2019 – September 16, 2019) recommends Yondelis as a single-agent for the treatment of leiomyosarcoma that has been treated previously with a anthracycline-containing regimen for disease that is not suitable for primary surgery, a radiologically isolated vaginal/pelvic recurrence, or isolated or disseminated metastases.<sup>2,4</sup>

## 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 indication(s). 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.

## RECOMMENDED AUTHORIZATION CRITERIA

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

### FDA-Approved Indications

**1. Liposarcoma or Leiomyosarcoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):

- A) The patient has unresectable or metastatic disease; AND
- B) Patient received a prior anthracycline-containing regimen (Note: Anthracyclines include doxorubicin, daunorubicin, epirubicin, idarubicin, valrubicin);<sup>1</sup> AND
- C) Yondelis is prescribed by or in consultation with an oncologist.

**Dosing.** Approve the following dosing regimens (A and B):

- A) Each individual dose must not exceed 1.5 mg/m<sup>2</sup> administered by intravenous infusion; AND

- B) Yondelis is administered a maximum of once in each 21-day cycle.<sup>1</sup>

### Other Uses with Supportive Evidence

**2. Soft Tissue Sarcoma.** (Note: Includes Extremity/Superficial Trunk, Head/Neck; Retroperitoneal/Intra-Abdominal; Angiosarcoma; and Rhabdomyosarcoma). Approve for 1 year if the patient meets the following criteria (A and B):

- A) Yondelis is used as single-agent palliative treatment;<sup>2,3</sup> AND  
 B) Yondelis is prescribed by or in consultation with an oncologist.

**Dosing.** Approve the following dosing regimens (A and B):

- A) Each individual dose must not exceed 1.5 mg/m<sup>2</sup> administered by intravenous infusion; AND  
 B) Yondelis is administered a maximum of once in each 21-day cycle.<sup>1</sup>

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### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Yondelis has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

- Coverage is not recommended for circumstances not listed in the Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

- Yondelis® [prescribing information]. Horsham, PA: Janssen Pharmaceuticals; December 2018.
- The NCCN Drugs and Biologics Compendium. © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 27, 2018. Search term: trabectedin.
- The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 4.2019 – September 12, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 29, 2019.
- The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (Version 4.2019 – September 16, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 29, 2019.

### HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New policy	--	12/12/2018
Annual revision	Soft tissue sarcoma: removed “for synchronous stage IV or recurrent disease with disseminated metastases” from criteria.	12/11/2019