

Trabectedin (Yondelis®)

Place of Service
Office Administration
Home Infusion Administration
Outpatient Facility Administration
Infusion Center Administration

HCPCS: J9352 per 0.1 mg

Condition listed in policy (see criteria for details)

- [Soft tissue sarcomas](#)
- [Uterine sarcoma](#)

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Alkylating agent

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Yondelis® (trabectedin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Soft tissue sarcoma

1. Diagnosis of one of the following:
 - a. Single agent use for myxoid liposarcoma, OR
 - b. Single agent use for solitary fibrous tumors, OR
 - c. Single agent use for extremities, body wall, head and neck soft tissue sarcomas (with non-specific histologies) and meets the following:
 - i. Advanced or metastatic disease, and
 - ii. Subsequent treatmentOR
 - d. Single agent use for retroperitoneal/intra-abdominal soft tissue sarcomas (non-specific histologies) and meets the following:
 - i. Recurrent unresectable or metastatic, and
 - ii. Subsequent treatmentOR
 - e. Single agent use for pleomorphic rhabdomyosarcoma and meets the following:
 - i. Advanced or metastatic disease, and
 - ii. Subsequent treatmentOR
 - f. Single agent use for liposarcoma or leiomyosarcoma (*For uterine leiomyosarcoma, refer to criteria under Uterine sarcoma*)
 - i. Unresectable or metastatic disease, and
 - ii. Subsequent treatmentOR
 - g. In combination with doxorubicin for leiomyosarcoma (*For uterine leiomyosarcoma, refer to criteria under Uterine sarcoma*)

Covered Doses

PHP Medi-Cal

Trabectedin (Yondelis®)

Up to 1.5 mg/m² IV every 21 days

Coverage Period

Indefinite

ICD-10:

C47.0, C47.10-C47.12, C47.20-C47.22, C47.3-C47.6, C47.8, C47.9, C48.0-C48.2, C48.8, C49.0, C49.10-C49.12, C49.20-C49.22, C49.3-C49.6, C49.8, C49.9, Z85.831

Uterine sarcoma

1. Diagnosis with histology of uterine leiomyosarcoma, **AND**
2. Disease is advanced, recurrent, metastatic or not suitable for primary surgery, **AND**
3. Either of the following:
 - a. Used in combination with doxorubicin for first line therapy, or
 - b. Used as a single agent therapy for second-line or subsequent therapy after treatment with an anthracycline-containing regimen (e.g., doxorubicin, epirubicin)

Covered Doses

Up to 1.5 mg/m² IV every 21 days

Coverage Period

Indefinite

ICD-10:

C53.0, C54.0-C54.3, C54.8, C54.9, C55, C78.00-C78.02, Z80.49

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Yondelis® (trabectedin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

1 mg (single-dose vial)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- National Comprehensive Cancer Network Drugs & Biologics Compendium. Yondelis® (2023). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version 1.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Uterine Neoplasms. (Version 1.2023). Available at <http://www.nccn.org>.

- Yondelis® (trabectedin) [Prescribing Information]. Horsham, PA: Janssen Pharmaceutical Companies; June 2020.

(7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- Section (2): Soft tissue sarcoma – Added coverage for treatment in combination with doxorubicin for leiomyosarcoma

Rationale: NCCN category 2A support

- Section (2): Uterine sarcoma – Expanded coverage to include advanced disease, and added coverage for first-line treatment in combination with doxorubicin

Rationale: NCCN category 2A support

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*