# Clinical Policy: Trabectedin (Yondelis)

Reference Number: LA.PHAR.204
Effective Date: 09.15.22
Last Review Date: ~~08.22~~06.02.23 Coding Implications
Line of Business: Medicaid Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

****Please note: This policy is for medical benefit****

**Description**
Trabectedin (Yondelis®) is an alkylating drug.

**FDA Approved Indication(s)**
Yondelis is indicated for the treatment of patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS) who received a prior anthracycline-containing regimen.

**Policy/Criteria**
~~***Prior authorization is required.***~~ *Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections that Yondelis is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Soft Tissue Sarcoma** (must meet all)**:**

1. Diagnosis of one of the following soft tissue sarcomas (STS) (a or b) *(see Appendix D for examples)*:
   a. STS that is unresectable or metastatic;
   b. Myxoid liposarcoma (LPS) that is ~~resectable~~one of the following (i, ii, or ~~high-~~ iii):
      i. Resectable;
      ii. High risk for metastatic disease ~~or local;~~
      ~~i.~~iii. Local recurrence;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. If uterine leiomyosarcoma (uLMS), member has received a prior anthracycline-containing regimen (e.g., doxorubicin);
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 1.5 mg/m$^2$ body surface area every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. ~~Refer to the off-label use policy if~~If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. ~~1.~~2.If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~): LA~~) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53 ~~for Medicaid.~~

## II. Continued Therapy

**A. Soft Tissue Sarcoma** (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Yondelis for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 1.5 mg/m$^2$ body surface area every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. ~~Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.~~
   ~~**Approval duration: Duration of request or 6 months (whichever is less)**~~; or~~
1. ~~Refer to the off-label use policy if~~If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~): LA~~) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53 ~~for Medicaid.~~

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy ~~–~~ LA.PMN.53 ~~for Medicaid, or evidence of coverage documents.~~

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration
LMS: leiomyosarcoma
LPS: liposarcoma
STS: soft tissue sarcoma
uLMS: uterine leiomyosarcoma

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| uLMS - examples of anthracycline-containing regimens: doxorubicin ± gemcitabine, olaratumab, fosfamide, or dacarbazine; epirubicin; liposomal doxorubicin | Varies | Varies |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*
- Contraindication(s): known hypersensitivity to trabectedin
- Boxed warning(s): none reported

*Appendix D: Types and Examples of STSs*
Examples are drawn from the National Comprehensive Center Network (NCCN) Soft Tissue Sarcoma Guideline, which cites the 2020 World Health Organization classification of tumors, and the Yondelis compendium.
- Smooth muscle tumors –- LMS
- Vascular tumors –- angiosarcoma
- Myo/fibroblastic tumors –- solitary fibrous tumor
- Skeletal muscle tumors –- rhabdomyosarcoma
- Adipocytic tumors – myxoid LPS
  - Begin in the adipose cells, usually occurring in the thigh and sometimes in the outer torso or buttocks
  - Myxoid LPS has a higher risk of metastasis to the spine compared to other STSs

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| LPS, LMS | 1.5 mg/m$^2$ (body surface area) as a 24-hour IV infusion every 21 days (3 weeks), until disease progression or unacceptable toxicity | Varies |

## VI. Product Availability
Single-dose vial with powder for injection: 1 mg

## VII. References
1. Yondelis Prescribing Information. Horsham, PA: Janssen Products, LP; June 2020. Available at: http://www.yondelis.com. Accessed November ~~9, 2021~~3, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed November ~~9, 2021~~3, 2022.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2022. Available at: www.nccn.org. Accessed November ~~9, 2021.~~3, 2022.

~~3.~~4.National Comprehensive Cancer Network. Uterine Neoplasms Version 1.2022. Available at: www.nccn.org. Accessed November 3, 2022.

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J9352 | Injection, trabectedin, 0.1 mg |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Corporate converted to local policy. | 09.22 | 09.15.22 |
| Template changes applied to other diagnoses/indications. References reviewed and updated.<br>Added verbiage this policy is for medical benefit only. | 06.02.23 | |

**Important Reminder**
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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