

## Clinical Policy: Trabectedin (Yondelis)

Reference Number: ERX.SPA.304

Effective Date: 03.01.19

Last Review Date: 02.22

Line of Business: Commercial, Medicaid

[Revision Log](#)

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

### Description

Trabectedin (Yondelis<sup>®</sup>) 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

*Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 or high risk for metastatic disease or local recurrence;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  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<sup>2</sup> 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

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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<sup>2</sup> 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
- Approval duration: Duration of request or 6 months (whichever is less); or**
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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 – ERX.PA.01 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

STS: soft tissue sarcoma

LMS: leiomyosarcoma

uLMS: uterine leiomyosarcoma

LPS: liposarcoma

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and 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 cite 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 <sup>2</sup> (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**

- Yondelis Prescribing Information. Horsham, PA: Janssen Products, LP; June 2020. Available at: <http://www.yondelis.com>. Accessed November 9, 2021.
- National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [www.nccn.org](http://www.nccn.org). Accessed November 9, 2021.
- National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2021. Available at: [www.nccn.org](http://www.nccn.org). Accessed November 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.13.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.29.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.14.20	02.21
1Q 2022 annual review: added myxoid LPS indication supported as category 2A in NCCN compendium; added Appendix D with STS examples; references reviewed and updated.	11.09.21	02.22

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

This policy is the property of Envolve Pharmacy Solutions. Unauthorized copying, use, and distribution of this Policy or any information contained herein is strictly prohibited. By accessing this policy, you agree to be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.

©2019 Envolve Pharmacy Solutions. All rights reserved. All materials are exclusively owned by Envolve Pharmacy Solutions and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Envolve Pharmacy Solutions. You may not alter or remove any trademark, copyright or other notice contained herein.