

Clinical Policy: Trabectedin (Yondelis)

Reference Number: LA.PHAR.204

Effective Date: 09.15.22

Last Review Date: 05.06.24

Line of Business: Medicaid

[Coding Implications](#)

[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

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 one of the following (i, ii, or iii):
 - i. Resectable;
 - ii. High risk for metastatic disease;
 - iii. Local recurrence;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. If uterine leiomyosarcoma (uLMS), prescribed in one of the following ways (a or b):
 - a. As a single agent AND member has received a prior anthracycline-containing regimen (e.g., doxorubicin);
 - b. In combination with doxorubicin;
5. Request meets one of the following (a or b):*
 - a. Dose does not exceed 1.5 mg/m² 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. 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) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

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/m² 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. 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) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

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

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 not be a formulary agent 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 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 October 16, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed November 15, 2023.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2023. Available at: www.nccn.org. Accessed November 21, 2023.
4. National Comprehensive Cancer Network. Uterine Neoplasms Version 1.2024. Available at: www.nccn.org. Accessed November 21, 2023.

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. Added verbiage this policy is for medical benefit only.	06.02.23	10.05.23
Annual review: for uLMS, clarified Yondelis prescribed as single agent for those who has received a prior anthracycline-containing regimen and added option for usage of Yondelis in combination with doxorubicin; references reviewed and updated.	05.06.24	

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.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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 clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

©2024 Louisiana Healthcare Connections. All rights reserved. All materials are exclusively owned by Louisiana Healthcare Connections 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 Louisiana Healthcare Connections. You may not alter or remove any trademark, copyright or other notice contained herein. Louisiana Healthcare Connections is a registered trademarks exclusively owned by Louisiana Healthcare Connections.