Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2021**
Policy Number: PA.CP.PHAR.204	**Effective Date: 01/01/2018** **Revision Date: 01/2021**
Policy Name: Trabectedin (Yondelis)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Trabectedin (Yondelis)

Reference Number: PA.CP.PHAR.204
Effective Date: 01/2018
Last Review Date: 01/2021

Coding Implications
Revision Log

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
It is the policy of Pennsylvania Health and Wellness 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 unresectable or metastatic soft tissue sarcomas (STS);
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*).

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Soft Tissue Sarcoma (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies ;
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*).

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to PA.CP.PMN.53

III. 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 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

IV. 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

V. Product Availability

Single-dose vial with powder for injection: 1 mg

VI. References

1. Yondelis Prescribing Information. Horsham, PA: Janssen Products, LP; June 2020. Available at: http://www.yondelis.com. Accessed November 14.2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed November 14, 2020.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2021. Available at: www.nccn.org. Accessed November 14, 2020.

4. National Comprehensive Cancer Network. Uterine Neoplasms Version 1.2021. Available at: www.nccn.org. Accessed November 14, 2020.

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	Approval Date
Added age requirement as safety and efficacy have not been established in pediatric patients. Removed criteria around specific FDA/NCCN uses that are under the purview of the provider, and added prescriber requirement to ensure appropriate use. Require that use be for palliative therapy or for metastatic or unresectable disease Re-auth: Modified requirement for no disease progression or unacceptable toxicity to requirement for positive response to therapy. Added max dosing criteria. References reviewed and updated		
1Q 2019 annual review; coverage of STS is expanded to encompass STS subtypes of non-specific histologies per NCCN; references reviewed and updated.	01/19	
1Q 2020 annual review: references reviewed and updated.	01/20	
1Q 2021 annual review: references reviewed and updated.	01/21	