Clinical Policy Title:	trabectedin
Policy Number:	RxA.324
Drug(s) Applied:	Yondelis®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Trabectedin (Yondelis®) is an alkylating drug. It is indicated for the treatment of patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS) who received a prior anthracycline-containing regimen.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
trabectedin (Yondelis®)	LPS, LMS	1.5 mg/m^2 (body surface area) as 24-hour intravenous infusion every 21 days (3 weeks), until disease progression or unacceptable toxicity. Hepatic impairment: Administer at 0.9 mg/m2 body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line in patients with moderate hepatic impairment	Varies

Dosage Forms

- Single-dose vial with powder for injection: 1 mg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of unresectable or metastatic soft tissue sarcoma (STS) (see Appendix D for examples);
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:
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance, 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*).

Approval duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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 generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to trabectedin.

- Boxed warning(s):
  - None reported.

APPENDIX D: General Information

- Indication covered under initial approval criteria:
  - Soft tissue sarcoma:
    - Extremity/Body Wall, Head/Neck
    - Retroperitoneal/Intra-Abdominal
    - Rhabdomyosarcoma
    - Angiosarcoma
    - Solitary Fibrous Tumor
  - Uterine Neoplasms - Uterine Sarcoma

References

1. Yondelis® Prescribing Information. Horsham, PA: Janssen Products, LP; June 2020. Available at http://www.yondelis.com. Accessed June 4, 2021.
2. Soft tissue sarcoma (Version 2.2021). In: National Comprehensive Cancer Network Guidelines. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf . Accessed June 4, 2021.
3. Trabectedin. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed June 4, 2021.
4. Uterine neoplasms (Version 2.2021). National Comprehensive Cancer Network Guidelines. Available at https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf . Accessed June 4, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	03/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 5. References were reviewed and updated.	07/17/2020	09/14/2020
Policy was reviewed: 1. Dosing Information dosing regimen was updated to	05/28/2021	09/14/2021

include hepatic dosing, “Hepatic impairment: Administer at 0.9 mg/m2 body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line in patients with moderate hepatic impairment”.

2. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy.
3. Initial Approval Criteria I.A.1 was updated to include “…(see Appendix D for examples)”.
4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".
5. Continued Therapy Approval Criteria was updated to remove HIM approval duration.
6. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance.."
7. • Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only".
8. Appendix D was updated to include “Indication covered under initial approval criteria: [Soft tissue sarcoma: Extremity/Body Wall, Head/Neck;

Retroperitoneal/Intra-Abdominal; Rhabdomyosarcoma; Angiosarcoma; Solitary Fibrous Tumor] / [Uterine Neoplasms - Uterine Sarcoma]". 9. References were reviewed and updated.		