RXADVANCE
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Clinical Policy Title:	trabectedin
Policy Number:	RxA.324
Drug(s) Applied:	Yondelis®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
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 a 24-hour IV infusion every 21 days (3 weeks), until disease progression or unacceptable toxicity.	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.

I. Initial Approval Criteria

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

1. Diagnosis of unresectable or metastatic soft tissue sarcoma (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

Commercial: 6 months

Medicaid: 6 months
HIM: 6 months

II. Continued Therapy Approval

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

1. 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
HIM: 12 months

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

APPENDIX D: General Information

- Not applicable

References

1. Yondelis Prescribing Information. Horsham, PA: Janssen Products, LP; June 2020. Available at http://www.yondelis.com. Accessed July 17, 2020.
2. Soft tissue sarcoma (Version 2.2020). In: National Comprehensive Cancer Network Guidelines. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf . Accessed July 17, 2020.
3. Trabectedin. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed July 17, 2020.
4. Uterine neoplasms (Version 1.2020). National Comprehensive Cancer Network Guidelines. Available at https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf . Accessed July 17, 2020.

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