Clinical Policy Title:	trabectedin
Policy Number:	RxA.324
Drug(s) Applied:	Yondelis®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

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).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network Guidelines. Soft tissue sarcoma Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed January 16, 2023.
2. National Comprehensive Cancer Network Guidelines. Uterine neoplasms Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed January 16, 2023.

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. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. Continued Therapy Approval Criteria was updated to remove HIM approval duration. 3. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance.." 4. References were reviewed and updated.	05/28/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	02/07/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	01/16/2023	04/13/2023

Policy was reviewed.	10/19/2023	10/19/2023