Clinical Policy: Trabectedin (Yondelis)

Reference Number: PA.CP.PHAR.204
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for trabectedin (Yondelis®).

FDA Approved Indication(s)
Yondelis is indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma 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 one of the following soft tissue sarcomas (STS) (a, b, c, or d):
   a. Liposarcoma;
   b. Leiomyosarcoma;
   c. Angiosarcoma;
   d. Rhabdomyosarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Prescribed as a palliative therapy or for disease that is unresectable or metastatic;
4. Age ≥ 18 years;
5. If uterine leiomyosarcoma, member has received a prior anthracycline-containing regimen (e.g., doxorubicin);
6. 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

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

II. Continued Approval

A. **All Indications** (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

Background
Description/Mechanism of Action:
Trabectedin is an alkylating drug that binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death.

Formulations:
Yondelis is supplied in a single-dose vial containing 1 mg trabectedin as a lyophilized powder for reconstitution.

Appendices
Appendix: Abbreviation key
STS: Soft tissue sarcoma

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
N/A	

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		

Reviews, Revisions, and Approvals	Date	Approval Date
response to therapy. Added max dosing criteria. References reviewed and updated		

References

1. Yondelis Prescribing Information. Horsham, PA: Janssen Products, LP; May 2017. Available at http://www.yondelis.com. Accessed October 30, 2017.
2. Soft tissue sarcoma (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed October 30, 2017.
3. Trabectedin. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed October 30, 2017.
4. Uterine neoplasms (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed October 30, 2017.