Clinical Policy: Trabectedin (Yondelis)

Reference Number: CP.PHAR.204
Effective Date: 05/16
Last Review Date: 03/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Yondelis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Meets a or b:
   a. FDA approved use (i, ii and iii):
      i. Diagnosis of liposarcoma or leiomyosarcoma;
      ii. Disease is unresectable or metastatic;
      iii. Evidence of disease progression on a prior anthracycline-containing regimen (e.g., doxorubicin, epirubicin);
   b. Off-label NCCN recommended use (one of the following diagnoses):
      i. Diagnosis of angiosarcoma as single-agent palliative therapy;
      ii. Diagnosis of retroperitoneal/intra-abdominal soft tissue sarcoma (STS) as single-agent palliative therapy for unresectable or progressive disease;
      iii. Diagnosis of rhabdomyoscarcoma as single-agent palliative therapy;
      iv. Diagnosis of STS of the extremity/superficial trunk or head/neck as single-agent palliative therapy for stage IV disease or recurrent disease with disseminated metastases.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

1. The following NCCN recommended uses meeting NCCN categories 1, 2a or 2b are approved per the CP.PHAR.57 Global Biopharm Policy:
   a. Uterine sarcoma.

II. Continued Approval

A. **All Indications** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. No disease progression or unacceptable toxicity.

Approval duration: 12 months

B. **Other diagnoses/indications** (must meet 1 or 2)**:**
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
   2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

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.

FDA Approved Indications:
Yondelis is an alkylating drug/intravenous formulation indicated for:
- Treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.

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
Policy developed.	04/16	05/16
Age and dose removed. Examples of anthracyclines added. Precautions removed given no black box warnings or contraindications other than hypersensitivity. Approval duration changed to 6 months and 12 months for initial and subsequent requests, respectively. NCCN recommended uses added.	03/17	04/17

References

1. Yondelis prescribing information. Horsham, PA: Janssen Products, LP; July 2016. Available at http://www.yondelis.com/prescribing-information.pdf. Accessed March 23, 2017.
2. Soft tissue sarcoma (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed March 23, 2017.
3. Trabectedin. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed March 23, 2017.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their

representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.