Clinical Policy: Trabectedin (Yondelis)

Reference Number: CP.PHAR.204
Effective Date: 05.01.16
Last Review Date: 02.18
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description
Trabectedin (Yondelis®) is an alkylating drug.

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
Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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. 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

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Soft Tissue Sarcoma (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Yondelis for one of the above listed STS;
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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
STS: soft tissue sarcoma

Appendix B: Therapeutic Alternatives
N/A
Appendix C: General Information
- Liposarcomas and leiomyosarcomas are also referred to as "L-type" sarcomas.
- The NCCN recommends Yondelis for the palliative treatment of extremity/superficial trunk, head/neck, and retroperitoneal/intra-abdominal L-type sarcomas [category 1]. For uterine leiomyosarcomas, Yondelis is recommended following anthracycline therapy for disease that is not suitable for primary surgery, that is a radiologically isolated vaginal/pelvic recurrence, or with metastases [category 2A].
- Yondelis is also recommended as palliative treatment for non-L-type sarcomas (e.g., angiosarcoma, rhabdomyosarcoma) [category 2A].

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Liposarcoma, leiomyosarcoma	1.5 mg/m^2 body surface area (reduce to 0.9 mg/m^2 in moderate hepatic impairment) as a 24-hour IV	Based on weight

Indication	Dosing Regimen	Maximum Dose
	infusion every 21 days (3 weeks), until disease progression or unacceptable toxicity	

VI. Product Availability

Single-dose vial with powder for injection: 1 mg

VII. 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.

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
J9352	Injection, trabectedin, 0.1 mg

Reviews, Revisions, and Approvals	Date	P&T 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
1Q18 annual review: - Initial: 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	10.30.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
-Re-auth: Added COC for STS. Modified requirement for no disease progression or unacceptable toxicity to requirement for positive response to therapy. Both: Added max dosing criteria. -References reviewed and updated		

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.