Medical Policy:

Yondelis (trabectedin) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.179	January 2, 2025	April 29, 2020

Definitions

Yondelis (trabectedin): is an alkylating agent originally derived from the sea squirt, Ecteinascidia turbinata. Yondelis causes alkylation by binding guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. This triggers a cascade of events that can affect the activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 40 billable units per 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

Yondelis *may be considered medically necessary when any of the below conditions are met:*

1. **Liposarcoma and Leiomyosarcoma (including uterine leiomyosarcoma)**
    A. Patient has advanced, inoperable, metastatic, or recurrent disease; **AND**
    B. Used for disease progression with an anthracycline containing regimen.
2. **Soft Tissue Sarcoma**
    A. The member has unresectable or metastatic soft tissue sarcoma including ONE of the following: **AND**
        i. Solitary Fibrous Tumors
        ii. Retroperitoneal/Intra-abdominal
        iii. Rhabdomyosarcoma
        iv. Extremity/Superficial Trunk, Head/Neck

Limitations/Exclusions

Yondelis (trabectedin) is not considered medically necessary when any of the following selection criteria is met:

1. Yondelis (trabectedin) is being used after disease progression with the same regimen.
2. Yondelis (trabectedin) is **NOT** being used via a central venous line.
3. Significant chronic liver disease, such as cirrhosis or active hepatitis requiring antiviral therapy.
4. Symptomatic congestive heart failure or life threatening arrhythmias.
5. Dosing exceeds single dose limit of Yondelis (trabectedin) 1.5 mg/m2.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

Yondelis authorization can be renewed based on the following criteria:

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Tumor response with disease stabilization or reduction of tumor size and spread; **AND**
3. Absence of unacceptable toxicity from the drug; **AND**
4. Left ventricular ejection fraction (LVEF) has not had an absolute decrease from baseline ≥ 15% and is not below the lower limit of normal and the patient does not have symptomatic LVEF changes.

Dosage/Administration

Indication	Dose
All Indications	1.1-1.5 mg/m^2 IV via a central venous line over 24 hours on day 1 repeated every 21 days until disease progression.

Applicable Procedure Codes

Code	Description
J9352	Injection, trabectedin, 0.1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
59676-0610-xx	Yondelis 1 mg vial for injection

ICD-10 Diagnoses

Code	Description
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C53.0	Malignant neoplasm of endocervix
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified

C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
Z85.831	Personal history of malignant neoplasm of soft tissue

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: Liposarcoma and Leiomyosarcoma (including uterine leiomyosarcoma): Removed "unresectable" and replaced with :advanced, inoperable" in the following statement: "Patient has advanced, inoperable, metastatic, or recurrent disease" Removed "single agent" from the following statement: "Used as a single agent for disease progression with an anthracycline containing regimen." Soft Tissue Sarcoma Updated to remove "Angiosarcoma" and add " Solitary Fibrous Tumors" Removed: "Used as a single agent therapy AND The member had disease progression with an anthracycline containing regimen." Limitations/Exclusions: removed the following:"Member must be 18 years of age or older , Concurrent use with DTIC (dacarbazine) or other chemotherapy., Poorly controlled hypertension or diabetes" RENEWAL CRITERIA: Updated ≥ 10% to ≥ 15% in the following statement: "Left ventricular ejection fraction (LVEF) has not had an absolute decrease from baseline 15% and is not below the lower limit of normal and the patient does not have symptomatic LVEF changes.
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/6/2023	Annual Review: Removed the word "palliative" in the following statement: Under Soft Tissue Sarcoma Initial Criteria. B. Used as a single agent palliative therapy AND
EmblemHealth & ConnectiCare	1/19/2023	Transfer to New Template
EmblemHealth & ConnectiCare	04/29/2020	Under Limitations/Eclusions added: Member must be 18 years of age or older.

References

1. Yondelis PI prescribing information. Janssen Biotech. Horsham, PA 2017.
2. Clinical Pharmacology Elsevier Gold Standard. 2018.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2018
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018