

## Medical Policy:

### Yondelis (trabectedin) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## 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/m<sup>2</sup>.
- 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  $\geq$  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 <sup>2</sup> 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 $\geq 10\%$ to $\geq 15\%$ 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