



## Yondelis® (trabectedin) (Intravenous)

Document Number: IC-0257

Last Review Date: 03/04/2019

Date of Origin: 12/04/2015

Dates Reviewed: 12/2015, 07/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019

### I. Length of Authorization

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

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 1 mg vial for injection: 4 vials every 21 days

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 40 billable units every 21 days

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years or older; **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits; **AND**
- Must be used as single agent therapy; **AND**

#### Liposarcoma & Leiomyosarcoma (including uterine leiomyosarcoma) †

- Patient has unresectable, metastatic or recurrent disease; **AND**
- Used as subsequent therapy after an anthracycline-containing regimen (e.g., doxorubicin, etc.)

#### Soft Tissue Sarcoma

- Used as palliative therapy; **AND**
- Patient has a diagnosis of one of the following sub-types of soft tissue sarcoma:
  - Angiosarcoma ‡
  - Rhabdomyosarcoma ‡
  - Retroperitoneal/Intra-abdominal ‡; **AND**

- Used for unresectable or progressive disease
- Extremity/Superficial Trunk, Head/Neck †; **AND**
  - Used for metastatic disease or recurrent disease with disseminated metastases

† FDA approved indication(s); ‡ Compendia recommended indication(s)

#### IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet criteria identified in Section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cardiomyopathy, rhabdomyolysis, hepatotoxicity and/or severe hepatic impairment, capillary leak syndrome (CPS), severe neutropenia/neutropenic sepsis, extravasation resulting in tissue necrosis, etc.; **AND**
- Left ventricular ejection fraction (LVEF) has not had an absolute decrease from baseline  $\geq$  15% or is not below the lower limit of normal (LLN) with an absolute decrease of  $\geq$  5% and the patient does not have symptomatic LVEF changes.

#### V. Dosage/Administration

| Indication      | Dose  |
|-----------------|---|
| All indications | 1.5 mg/m <sup>2</sup> administered intravenously (IV) over 24 hours through a central venous line every 21 days, until disease progression or unacceptable toxicity |

#### VI. Billing Code/Availability Information

Jcode:

- J9352 - Injection, trabectedin, 0.1 mg: 1 billable unit = 0.1 mg

NDC:

- Yondelis 1 mg vial for injection: 59676-0610-xx

#### VII. References

1. Yondelis [package insert]. Horsham, PA; Janssen Products, LP; January 2019. Accessed January 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium<sup>®</sup>) trabectedin. National Comprehensive Cancer Network, 2018. The NCCN Compendium<sup>®</sup> is a derivative work of the NCCN Guidelines<sup>®</sup>. NATIONAL COMPREHENSIVE CANCER NETWORK<sup>®</sup>, NCCN<sup>®</sup>, and NCCN GUIDELINES<sup>®</sup> are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2019.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 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                                  |

| ICD-10  | ICD-10 Description                                      |
|---------|---|
| 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   |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |   |
|---|---|---|
| Jurisdiction  | Applicable State/US Territory   | Contractor  |
| E (1)   | CA, HI, NV, AS, GU, CNMI  | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ  | Noridian Healthcare Solutions, LLC                |
| 5   | KS, NE, IA, MO  | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6   | MN, WI, IL  | National Government Services, Inc. (NGS)          |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                           |
| 8   | MI, IN  | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)   | FL, PR, VI  | First Coast Service Options, Inc.                 |
| J (10)  | TN, GA, AL  | Palmetto GBA, LLC                                 |
| M (11)  | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                                 |
| L (12)  | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)   | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)          |

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

| <b>Jurisdiction</b> | <b>Applicable State/US Territory</b> | <b>Contractor</b>       |
|---------------------|--------------------------------------|-------------------------|
| 15                  | KY, OH                               | CGS Administrators, LLC |