Prior Authorization Approval Criteria

Yondelis (trabectedin)

Generic name: Trabectedin
Brand name: Yondelis
Medication class: Antineoplastic, alkylating agent
FDA-approved uses: Treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Must be clinically diagnosed with unresectable or metastatic liposarcoma or leiomyosarcoma
- Must have received prior anthracycline-containing regimen
- Must be ≥18 years of age
- Must be prescribed by an oncologist

Criteria for continuation of therapy:

- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

Caution:

- Neutropenic sepsis: Severe, and fatal, neutropenic sepsis may occur. Monitor neutrophil count during treatment
- Rhabdomyolysis: Rhabdomyolysis may occur
- Hepatotoxicity: Hepatotoxicity may occur
- Cardiomyopathy: Severe and fatal cardiomyopathy can occur
- Embryofetal toxicity: Can cause fetal harm. Advise of potential risk to a fetus and use effective contraception

Approval Duration:

- Initial 6 months
- Renewal 1 year

Benefit Type:

- Medical

** Off-label Use:

Fallon may authorize coverage of the requested medication for use in other cancer diagnoses with submitted documentation that the drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

If the requested off-label use is not acknowledged by the NCCN Drugs and Biologics Compendium, Fallon will abide by the Centers for Medicare and Medicaid Services (CMS) guidance or Massachusetts
regulations¹ accepting documentation of recommended off-label use of the requested medication in any one of the following:

1. One of the following standard reference compendia:
   - American Hospital Formulary Service – Drug information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - Wolters Kluwer Lexi-Drugs

2. Peer-reviewed published medical literature determined by Fallon that sufficient evidence exists to support use.

¹Reference: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K
accessed 7/7/2017

Adopted: 3/9/16

Revised:

Effective: 3/9/16
Reviewed: 9/13/17 updated criteria for use, continuation of therapy and approval duration, removed contraindications, not approved if and special considerations and added benefit type