I. Medication Description

Yondelis (trabectedin) is an alkylating agent which binds and alkylates DNA, resulting in an unnatural bending of the DNA helix. This deformation disrupts DNA binding proteins, transcription factors, and DNA repair pathways, disrupting the cell cycle and leading to eventual cell death.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Yondelis is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for 1.5 mg/m2 every 21 days.

V. Coverage Duration

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

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information
• Available as 1mg vials
• J9352: 1 billing unit = 0.1 mg
• Pertinent diagnoses:
  o Angiosarcoma: C48.0-C48.2, C49.0, C49.10-C49.12, C49.20-C49.22, C49.3-C49.6, C49.8, C49.9, Z85.831
  o Retroperitoneal/Intra-abdominal soft tissue sarcoma: C47.0, C47.10-C47.12, C47.20-C47.22, C47.3-C47.6, C47.8, C47.9, C48.0-C48.2, C48.8, C49.4-C49.6, C49.8, C49.9, Z85.831
  o Rhabdomyosarcoma: C48.0-C48.2, C48.8, C49.9, Z85.831
  o Soft tissue sarcoma of the Extremity/Superficial Trunk, Head/Neck: C47.0, C47.10-C47.12, C47.20-C47.22, C47.3-C47.6, C47.8, C47.9, C49.0, C49.10-C49.12, C49.20-C49.22, C49.3, C49.6, C49.9, Z85.831
  o Uterine sarcoma: C53.0, C54.0-C54.3, C54.8, C54.9, C55, C78.00-C78.02, Z80.49

VIII. Summary of Policy Changes

• 3/15/16: new policy
• 6/15/16: no policy changes
• 4/5/17: updated J code
• 5/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.