Draft Revision Policy: Do Not Implement

Trabectedin (Yondelis®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Yondelis is indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.

Compendial Uses

- Uterine sarcoma
- Soft tissue sarcoma
  - Extremity/body wall, head/neck
  - Retroperitoneal/intra-abdominal
  - Rhabdomyosarcoma
  - Solitary fibrous tumor
  - Liposarcoma
  - Epithelioid hemangioendothelioma
- Ovarian cancer

COVERAGE CRITERIA

Soft Tissue Sarcoma

Authorization of 12 months may be granted for treatment of liposarcoma or leiomyosarcoma when all of the following criteria are met:

- The disease is unresectable or metastatic.
- The member has received a prior anthracycline-containing regimen.

Authorization of 12 months may be granted when used as a single agent for the treatment of myxoid liposarcoma when any of the following are met:

- The requested medication will be used as neoadjuvant or adjuvant therapy for retroperitoneal/intra-abdominal sarcoma.

- The requested medication will be used as neoadjuvant, adjuvant, or primary therapy for extremity/body wall, head/neck sarcoma.

Authorization of 12 months may be granted when used as single-agent palliative therapy for the treatment of one of the following:

- Solitary fibrous tumor.
- Advanced/metastatic pleomorphic rhabdomyosarcoma.
- Extremity/body wall, head/neck sarcoma for advanced/metastatic disease with disseminated metastases.
- Retroperitoneal/intra-abdominal sarcoma for ~~recurrent~~ unresectable, progressive, or stage IV disease.

Authorization of 12 months may be granted when used in combination with doxorubicin for the treatment of leiomyosarcoma when any ~~either~~ of the following are met:

- The requested medication will be used as first-line treatment for advanced or metastatic therapy.
- The requested medication will be used as alternative systemic therapy for unresectable or progressive disease.
- The requested medication will be used as palliative systemic therapy for stage IV with disseminated metastases or recurrent metastatic disease with disseminated metastases for extremity/body wall, head/neck sarcoma.
- The requested medication will be used as palliative treatment for stage IV disease with disseminated metastases for retroperitoneal/intra-abdominal sarcoma.

Authorization of 12 months may be granted when used as single-agent therapy when any of the following are met:

- The requested medication will be used for dedifferentiated liposarcoma.
- The requested medication will be used for epithelioid hemangioendothelioma.

Uterine Sarcoma

Authorization of 12 months may be granted for subsequent therapy as a single-agent for treatment of uterine leiomyosarcoma when all of the following criteria are met:

- ~~The member has been treated with a prior anthracycline-containing regimen~~
- The member has advanced, recurrent, metastatic or inoperable disease
- One of the following is met:
  - The member has known or suspected extrauterine disease.
  - The disease is not suitable for primary surgery.
  - The requested medication will be used as additional therapy following total hysterectomy with or without bilateral salpingo-oophorectomy.
  - The member has resectable isolated metastases and the requested medication will be used preoperatively or postoperatively.
  - The member has unresectable isolated metastases or disseminated disease.
  - The member has radiologically isolated vaginal/pelvic recurrence.

Authorization of 12 months may be granted in combination with doxorubicin for treatment of uterine leiomyosarcoma when all of the following criteria are met:

- The member has advanced, recurrent, metastatic or inoperable disease.
- One of the following is met:
  - The member has known or suspected extrauterine disease.
  - The disease is not suitable for primary surgery.
  - The requested medication will be used as additional therapy following total hysterectomy with or without bilateral salpingo-oophorectomy.

- The member has resectable isolated metastases and the requested medication will be used preoperatively or postoperatively.
- The member has unresectable isolated metastases or disseminated disease.
- The member has radiologically isolated vaginal/pelvic recurrence.

Ovarian Cancer

Authorization of 12 months may be granted for treatment of recurrent, platinum-sensitive ovarian cancer when used in combination with pegylated liposomal doxorubicin.

CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen and
  - No evidence of disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Yondelis [package insert]. Horsham, PA: Janssen Products, LP; June 2020.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 15, 2025.
3. ~~IBM~~ Micromedex® ~~DRUGDEX ®~~ (electronic version). Merative , Ann Arbor, Michigan, ~~IBM Watson Health, Greenwood Village, Colorado~~, USA. Available at https://www.micromedexsolutions.com. / (cited:07/15/2025) ~~Accessed: July 21, 2024~~.

EFFECTIVE DATE

ID_CHS_2025