Reference number
4838-A

Aetna Medicare Part B Drug Criteria

Yondelis

This policy is for Aetna Medicare members. Find the Aetna Commercial Medical Drug Criteria.

For Aetna Medicare members, National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) will be applied to Part B drug requests when applicable. Aetna Medicare Part B Drug Criteria documents will be used in the absence of an NCD and LCD.

POLICY

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-Counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Yondelis	trabectedin

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[1]

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

Compendial Uses[2,3]

- Uterine sarcoma
- Soft tissue sarcoma
    - Extremity/body wall, head/neck
    - Retroperitoneal/intra-abdominal
    - Rhabdomyosarcoma
    - Solitary fibrous tumor

  - Liposarcoma
  - Epithelioid hemangioendothelioma
- Ovarian cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Soft Tissue Sarcoma[1-3]

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 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 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[2]

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 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[3]

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.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Yondelis.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Uterine neoplasms
- NCCN Guideline: Soft tissue sarcoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Yondelis are covered in addition to the following:

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

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Yondelis to treat soft tissue sarcoma and uterine sarcoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Yondelis to treat ovarian cancer can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/15/2025).

DOCUMENT HISTORY

Revised:	December 2025
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See Evidence of Coverage for a complete description of plan benefits, exclusions, limitations and conditions of coverage. Plan features and availability may vary by service area.