POLICY NUMBER UM ONC_1290	**SUBJECT** Yondelis™ (trabectedin)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 04/13/16, 02/06/17, 01/29/18, 02/14/18, 02/06/19, 12/11/19, 02/12/20	**APPROVAL DATE** February 12, 2020	**EFFECTIVE DATE** March 01, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 04/13/16, 02/06/17, 01/29/18, 02/14/18, 02/06/19, 12/11/19, 02/12/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Yondelis (trabectedin) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **Soft Tissue Sarcoma**
    a. The member has unresectable or metastatic soft tissue sarcoma (Angiosarcoma, Retroperitoneal/Intra-abdominal, Rhabdomyosarcoma, and sarcoma of the extremity/superficial trunk, head/neck) **AND**
    b. Yondelis (trabectedin) is being used as a single agent palliative therapy **AND**
    c. The member had disease progression during or after an anthracycline containing regimen.
2. **Uterine Sarcoma**
    a. The member has unresectable or metastatic uterine leiomyosarcoma **AND**
    b. Yondelis (trabectedin) is being used as single agent for members with disease progression during or after an anthracycline containing regimen.

III. EXCLUSION CRITERIA

1. Yondelis (trabectedin) is being used after disease progression with the same regimen.
2. Concurrent use with DTIC (dacarbazine) or other chemotherapy.
3. Significant chronic liver disease, such as cirrhosis or active hepatitis requiring antiviral therapy.
4. Dosing exceeds single dose limit of Yondelis (trabectedin) 1.5 mg/m2.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Yondelis PI prescribing information. Janssen Biotech. Horsham, PA 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.