POLICY NUMBER UM ONC_1205	**SUBJECT** Halaven™ (eribulin)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 02/08/12, 12/11/13, 03/11/15, 04/11/16, 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) 02/08/12, 12/11/13, 03/11/15, 04/11/16, 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 Halaven (eribulin) 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. Breast Cancer

a. The member has recurrent or metastatic breast cancer, and Halaven (eribulin) is being used for members with HER2-negative disease**. OR**

b. The member has recurrent or metastatic breast cancer, and Halaven (eribulin) is being used in combination with trastuzumab for members with HER2-positive disease **AND**

c. The member has failed both an anthracycline and a taxane in either the metastatic or adjuvant setting.

2. Soft Tissue Sarcoma

a. The member has Angiosarcoma, Rhabdomyosarcoma or Soft tissue sarcoma of the extremity/ trunk/head/neck/retroperitoneal/intra-abdominal region **AND**

i. Halaven (eribulin) is being used as a single agent for palliative therapy in the member with disease progression on an anthracycline-containing regimen.

III. EXCLUSION CRITERIA

1. The member did not receive-prior treatment with an anthracycline AND taxane based chemotherapy for breast cancer or prior anthracycline containing regimen for soft tissue sarcoma.
2. Dosing exceeds single dose limit of Halaven (eribulin) 1.4 mg/m^2.
3. Member has disease progression while on Halaven (eribulin).

4. 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 – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Halaven prescribing information... Bristol-Myers Squibb Company. Princeton, NJ. 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.