POLICY NUMBER UM ONC_1240	**SUBJECT** Synribo™ (omacetaxine)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 04/10/13, 07/24/14, 12/18/15, 12/21/16, 11/08/17, 10/04/18, 09/11/19, 12/11/19, 06/10/20	**APPROVAL DATE** June 10, 2020	**EFFECTIVE DATE** June 26, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 04/10/13, 07/24/14, 12/18/15, 12/21/16, 11/08/17, 10/04/18, 09/11/19, 12/11/19, 06/10/20	
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 Synribo (omacetaxine) 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**

b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**

c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand-name drugs.

2. Chronic Myelogenous Leukemia

a. The member has chronic phase or accelerated phase CML **OR** is post-transplant **AND**

b. The member is Philadelphia chromosome or BCR-ABL positive **AND**

i. The member has experienced disease progression / intolerance to three or more of the following tyrosine kinase inhibitors: Gleevec (imatinib), Tasigna (nilotinib), or Bosulif (bosutinib) **OR**

ii. The member has a T315I mutation.

III. EXCLUSION CRITERIA

1. Disease progression while taking Synribo (omacetaxine).
2. Concurrent use with Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), or Bosulif (bosutinib).
3. Dosing exceeds single dose limit of Synribo (omacetaxine) 1.25 mg/m^2.
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 – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

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