Neighborhood Health Plan OF RHODE ISLAND™

New Century Health

Policy #UM ONC_1207
PROPRIETARY & CONFIDENTIAL

POLICY NUMBER UM ONC_1207	**SUBJECT** Zelboraf™ (vemurafenib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 02/08/12, 02/04/13, 12/11/13, 03/16/15, 07/25/16, 06/28/17, 07/27/17, 07/19/18, 06/12/19, 12/11/19, 06/10/20	**APPROVAL DATE** June 10, 2020	**EFFECTIVE DATE** June 26, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 02/08/12, 02/04/13, 12/11/13, 03/16/15, 07/25/16, 06/28/17, 07/27/17, 07/19/18, 06/12/19, 12/11/19, 06/10/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS	**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 Zelboraf (vemurafenib) 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. Malignant Melanoma

a. **NOTE: Per NCH Policy & NCH Pathway, Vemurafenib +Cobimetinib is the preferred combination therapy for BRAF V600 E positive melanoma, both in the first line and subsequent line settings.**

b. Zelboraf (vemurafenib) may be used in combination with cobimetinib in a member with BRAF V600E positive metastatic/recurrent/unresectable malignant melanoma for **ONE** of the following:

i. First line therapy

ii. Second-line or subsequent line therapy if the member has not been treated previously with vemurafenib + cobimetinib OR another combination of a BRAF inhibitor + MEK inhibitor.

3. Erdheim-Chester Disease (ECD)

a. Zelboraf (vemurafenib) may be used as a single agent in member with BRAF V600 mutation positive ECD.

III. EXCLUSION CRITERIA

1. Member has wild-type BRAF.
2. Use of Zelboraf (vemurafenib) as a single agent in metastatic/recurrent/unresectable BRAFV600E + malignant melanoma.
3. Dosing exceeds single dose limit of Zelboraf (vemurafenib) 960 mg or daily dose limit of 1920 mg per day.
4. Treatment exceeds the maximum limit of 240 (240 mg) capsules a month.
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. Zelboraf prescribing information. South San Francisco, CA: Genentech USA, Inc. 2020
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.