| POLICY NUMBER<br>UM ONC_1043 | SUBJECT<br>Tarceva™ (Erlotinib) | | DEPT/PROGRAM<br>UM Dept | PAGE 1 OF 2 |
|---|---|---|---|---|
| DATES COMMITTEE REVIEWED<br>01/12/11, 05/09/12, 11/01/13, 03/06/15, 03/27/15, 04/12/16, 02/08/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 07/08/20 | APPROVAL DATE<br>July 8, 2020 | EFFECTIVE DATE<br>July 31, 2020 | COMMITTEE APPROVAL DATES (latest version listed last)<br>01/12/11, 05/09/12, 11/01/13, 03/06/15, 03/27/15, 04/12/16, 02/08/17, 01/10/18, 02/13/19, 12/11/19, 02/12/20, 07/08/20 | |
| PRIMARY BUSINESS OWNER: UM<br>APPROVED BY: Dr. Andrew Hertler | | COMMITTEE/BOARD APPROVAL<br>Utilization Management Committee | | |
| URAC STANDARDS<br>HUM 1 | | NCQA STANDARDS<br>UM 2 | ADDITIONAL AREAS OF IMPACT | |
| CMS REQUIREMENTS | STATE/FEDERAL REQUIREMENTS | | APPLICABLE LINES OF BUSINESS<br>All | |

## I. PURPOSE

To define and describe the accepted indications for Tarceva (erlotinib) 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 dug alternatives are preferred over Brand name drugs.

### 2. Non-Small Cell Lung Cancer (NSCLC)

**NOTE: Per NCH Pathway & NCH Policy, the preferred agent for first line therapy of recurrent/metastatic, EGFR mutation positive Non-Small Cell Lung Cancer is Tagrisso (osimertinib).**

**NOTE: Tarceva (erlotinib) + Avastin (bevacizumab) is a non-preferred regimen per NCH Policy & NCH Pathway.**

a. Tarceva (erlotinib) may be used as a single agent for recurrent/metastatic, EGFR mutation positive NSCLC if the member has an intolerance/contraindication to Tagrisso(osimertinib).

**3. Bone Cancer**

a. Tarceva (Erlotinib) is being used as a single agent the treatment of recurrent chordoma.

## III. EXCLUSION CRITERIA

1. Off-label indications for Tarceva (Erlotinib) in pancreatic and kidney cancers shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
2. Tarceva (Erlotinib) is being used concurrently with other tyrosine kinase inhibitors such as Iressa (Gefitinib), Gleevec (Imatinib), Sprycel (Dasatinib), Tasigna (Nilotinib), Tykerb (Lapatinib), Sutent (Sunitinib), Nexavar (Sorafenib), Votrient (Pazopanib), or with chemotherapy.
3. Dosing exceeds single dose limit of Tarceva (Erlotinib) 150 mg.
4. Treatment with Tarceva (erlotinib) exceeds the maximum duration limit of 180 (25 mg ), 30 (100 mg), 30 (150 mg) tablets 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. Tarceva prescribing information. Genetech, Inc. 2018.
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.