POLICY NUMBER UM ONC_1133	SUBJECT Erbitux™ (cetuximab)		DEPT/PROGRAM UM Dept	Page 1 of 3
DATES COMMITTEE REVIEWED 07/22/11, 01/02/13, 03/13/13, 07/24/14, 12/16/15, 12/20/16, 12/14/17, 11/08/18, 09/30/19, 10/09/19, 12/11/19, 03/11/20, 05/13/20	APPROVAL DATE May 13, 2020	EFFECTIVE DATE May 29, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 07/22/11, 01/02/13, 03/13/13, 07/24/14, 12/16/15, 12/20/16, 12/14/17, 11/08/18, 09/30/19, 10/09/19, 12/11/19, 03/11/20, 05/13/20	
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 Erbitux (cetuximab) 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. **Head and Neck Cancers**
    a. The member has non-nasopharyngeal squamous cell carcinoma of the head and neck Erbitux (cetuximab) may be used in **ANY** of the following situations:
        i. As a part of primary/definitive concurrent chemoradiation (Erbitux + Radiation) as a single agent **OR**

ii. Sequential chemoradiation (Erbitux + Radiation) following induction chemotherapy **OR**

iii. For recurrent/metastatic disease in combination with platinum- based chemotherapy with/without Keytruda (pembrolizumab) **OR** as a single agent.

3. **Colorectal Cancer**

a. The member has stage IV metastatic colorectal cancer and Erbitux (cetuximab) may be used for tumors expressing KRAS/NRAS wild-type gene as **ONE** of the following:

i. Initial therapy:

A. In combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) regimen **OR**

B. As a single agent.

ii. Recurrent therapy (not previously treated with cetuximab or panitumumab)

A. For disease previously treated with oxaliplatin based chemotherapy without irinotecan (i.e. FOLFOX OR CAPEOX/XELOX): used in combination with FOLFIRI (fluorouracil, leucovorin, and irinotecan), irinotecan. or as a single agent **OR**

B. For disease previously treated with irinotecan- based chemotherapy without oxaliplatin (i.e. FOLFIRI): used in combination with irinotecan, FOLFOX (fluorouracil, leucovorin, and oxaliplatin) regimen, or as a single agent **OR**

C. As a single agent or in combination with irinotecan for member who has failed or cannot tolerate irinotecan and oxaliplatin based regimens.

b. The member has unresectable, advanced, or metastatic KRAS/NRAS Wild-Type and BRAF V600E mutation positive colorectal cancer and Erbitux (cetuximab) may be used in combination with Encorafenib after prior therapy in the metastatic setting. **NOTE: Cetuximab + Encorafenib is NCH preferred L1 pathway for second-line or subsequent therapy in the metastatic setting.**

III. EXCLUSION CRITERIA

1. Off-label indications for Erbitux (cetuximab) in NSCLC.
2. Disease progression with Erbitux (cetuximab) or Vectibix (panitumumab) containing regimen.
3. Pre-operative chemotherapy for potentially resectable liver metastases from KRAS/NRAS wild-type colorectal cancer.
4. Dosing exceeds single dose limit of Erbitux (cetuximab) as follows: a. Loading Dose of 400 mg/m^2 x 1 dose b. Subsequent doses of 250 mg/m2 weekly **OR** 500 mg/m^2 every 2 weeks.
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. Erbitux (cetuximab) prescribing information. ImClone LLC, Branchburg, 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.