Drug Policy:

Erbitux™ (cetuximab)

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, 11/11/20	**APPROVAL DATE** November 11, 2020	**EFFECTIVE DATE** November 30, 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, 11/11/20	
PRIMARY BUSINESS OWNER: UM		**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** Commercial, Exchange, Medicaid	

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 Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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

2. 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
3. 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
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Head and Neck Cancers

1. Note: Randomized data have shown that Erbitux (cetuximab) + radiation therapy is inferior to cisplatin + radiation therapy. Therefore, the use of Erbitux (cetuximab) + radiation therapy for curative intent is only recommended for members who have a contraindication to cisplatin use.
2. The member has non-nasopharyngeal squamous cell carcinoma of the head and neck Erbitux (cetuximab) may be used in ANY of the following situations:
   a. As a part of primary/definitive/curative-intent concurrent chemoradiation (Erbitux + Radiation) as a single agent for members with a contraindication to cisplatin use OR
   b. For recurrent/metastatic disease as a single agent.

C. Colorectal Cancer

1. The member has stage IV, KRAS/NRAS Wild-Type metastatic colorectal cancer and Erbitux (cetuximab) is being used as a single agent or in combination with FOLFIRI, FOLFOX, or irinotecan in the initial or subsequent line setting, except for members who have experienced disease progression on prior therapy with Erbitux (cetuximab) or Vectibix (panitumumab).
2. 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 Braftovi (encorafenib) after prior therapy in the metastatic setting. NOTE: Erbitux (cetuximab) + Braftovi (encorafenib) is NCH preferred L1 pathway for second-line or subsequent therapy in the metastatic setting.

III. EXCLUSION CRITERIA

A. Disease progression on prior therapy (single agent or multiagent therapy) that included Erbitux (cetuximab) or Vectibix (panitumumab).

B. Pre-operative chemotherapy for potentially resectable liver metastases from KRAS/NRAS wild-type colorectal cancer.

C. 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/m^2 weekly OR 500 mg/m^2 every 2 weeks.

D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Erbitux (cetuximab) prescribing information. ImClone LLC, Branchburg, NJ 2020.

B. Clinical Pharmacology Elsevier Gold Standard 2020.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2020.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2020.