POLICY NUMBER UM_1285	SUBJECT Portrazza™ (necitumumab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATE REVIEWED 3/22/16	APPROVAL DATE 3/23/16	EFFECTIVE DATE 3/23/16	REVISION DATES (latest version listed last) 3/22/16	
PRIMARY BUSINESS OWNER: APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Oncology	

I. PURPOSE

To define and describe the accepted indications for Portrazza (necitumumab) usage in the treatment of cancer.

II. DEFINITIONS

Portrazza (necitumumab): is a recombinant IgG EGFR monoclonal antibody which binds to the ligand binding site of the EGFR receptor to prevent receptor activation and downstream signaling.

Portrazza (necitumumab) is FDA approved in combination with gemcitabine and cisplatin for first-line treatment of people with metastatic squamous non-small cell lung cancer (NSCLC).

Portrazza (necitumumab) is available in 800 mg/ 50 ml intravenous solution.

III. POLICY

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. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must be supported by, at minimum, two peer reviewed citations. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Portrazza (necitumumab) may be considered medically necessary when any of the following selection criteria is met:

1. Non-Small Cell Lung Cancer (NSCLC)
    a. The member has recurrent or metastatic NSCLC and Portrazza (necitumumab) is being used in combination with gemcitabine and cisplatin as **ONE** of the following:
        i. First line therapy
        ii. Subsequent therapy for sensitizing EGFR mutation-positive tumors **AND** prior erlotinib, afatinib, or gefitinib therapy
        iii. Subsequent therapy for ALK-positive tumors **AND** prior crizotinib therapy.

Exclusion Criteria: Portrazza (necitumumab) is not considered medically necessary when any of the following selection criteria is met:

1. Disease progression while taking Portrazza (necitumumab).
2. Dosing exceeds single dose limit of 800 mg.
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable

IV. PROCEDURE

Requests for Portrazza (necitumumab) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration:** 800 mg infused intravenously over 60 minutes on days 1 and 8 of each 3 week cycle.
2. **Dosage Adjustments:**
    a. Infusion-related reaction (grade 1): Reduce infusion rate by 50%.
    b. Infusion-related reaction (grade 2): Stop infusion until resolution to grade 1 or 0, then resume infusion at a 50% reduced rate for all subsequent infusions.
    c. Infusion-related reaction (grade 3 or 4): Permanently discontinue.
    d. Dermatologic toxicity (grade 3 rash or acneiform rash): Withhold treatment until resolution to grade 2 or less, then resume at a reduced dose of 400 mg for at least 1 treatment cycle; if symptoms do not worsen may increase dose for subsequent cycles to 600 mg and 800 mg; permanently discontinue if symptoms do not resolve to grade 2 or less within 6 weeks OR if symptoms worsen or are not tolerable at the 400 mg dosage.
    e. Dermatologic toxicity (grade 4 or grade 3 skin induration or fibrosis): Permanently discontinue.
3. Monitoring
    a. Monitor for serum electrolytes (magnesium, potassium, and calcium) for cardiopulmonary arrest and hypomagnesaemia for at least 8 weeks after completion of therapy. Withhold therapy if electrolyte abnormalities are at grade 3 or 4. Therapy can be resumed if electrolyte abnormalities are improved to grade ≤2.
    b. Monitor for venous and arterial thromboembolic events (VTE).
    c. Monitor for Dermatological toxicities (skin reactions, indurations, or fibrosis).
    d. Monitor for Infusion-related reactions. Monitor for Embryo-fetal toxicity.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

VII. REFERENCES

1. PI prescribing information accessed on 3/22/16: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125547s000lbl.pdf
2. Clinical Pharmacology Elsevier Gold Standard. 2016.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2016.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2016.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists. Bethesda, MD. 2016.
6. Lexicomp Online® , Pediatric & Neonatal Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc. 2016.