CLINICAL MEDICATION POLICY	
Policy Name:	Portrazza™ (Necitumumab)
Policy Number:	MP-021-MD-PA
Responsible Departments:	Medical Management Medical Policy; Clinical Pharmacy
Provider Notice Date:	06/01/2017
Original Effective Date:	07/01/2017
Annual Approval Date:	01/30/2018
Revision Date:	12/19/2016
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ may provide coverage under the medical or pharmacy benefits of the Company's Medicaid products for medically necessary Portrazza™ (necitumumab) intravenous infusion administration.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

Medical Necessity – A service or benefit is medically necessary if it is compensable under the Medical Assistance program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability.
- The service or benefit will assist the patient to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the patient and those functional capacities that are appropriate for patients of the same age.

Portrazza – An epidermal growth factor receptor (EGFR) antagonist indicated, in combination with gemcitabine and cisplatin, for the first-line treatment of patients with non-small cell lung cancer (NSCLC).

PROCEDURES

1. Portrazza is considered medically necessary as an intravenous infusion for the treatment of metastatic or advanced non-small cell lung cancer (NSCLC) when the member meets the following criteria:
    A. The member is aged 18 years or older; AND
    B. The prescriber is a hematologist/oncologist; AND
    C. The member will receive or has received a cardiac assessment prior to initiation of Portrazza; AND
    D. The member will have routine monitoring of serum electrolytes prior to each dose of Portrazza during treatment and for at least eight weeks following completion of treatment; AND
    E. Portrazza will be used in combination with gemcitabine and cisplatin for first-line treatment; AND
    F. The prescriber provides documentation to the member explaining why the addition of Portrazza to cisplatin and gemcitabine as first-line therapy has benefits outweighing the increased risk of toxicity, adverse effects, and documented limited efficacy; AND
    G. The prescriber is aware that the National Comprehensive Cancer Network does not support the addition of a third agent to cisplatin and gemcitabine for the first-line treatment of metastatic squamous cell NSCLC; AND
    H. The medication dosing is within the following prescribing-supported parameter:
        1) The dose does not exceed 800 mg per dose
        2) The dose does not exceed 2 doses every 3 weeks

2. When the Portrazza is not covered
   Portrazza is not covered for conditions other than those listed above because the scientific evidence has not been established.

   Coverage may be provided for any non-FDA labeled indication or a medically accepted indication that is supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis for which it is prescribed and will be reviewed on a case-by-case basis to determine medical necessity.

3. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

4. Place of Service
   The place of service for the administration of Portrazza is outpatient.

Governing Bodies Approval
On November 24, 2015 the FDA approved Portrazza in combination with gemcitabine and cisplatin to treat patients with advanced (metastatic) squamous non-small cell lung care (NSCLC) who have not previously received medication specifically for treating their advanced lung cancer.

CODING REQUIREMENTS

Procedure Codes:

CPT & HCPCS Codes	Description
J3490	Unclassified drugs
J3590	Unclassified biologics
J9999	Not otherwise classified, antineoplastic drugs
C9475	Injection, Necitumumab, 1 mg
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

Diagnosis Codes:

ICD-10 Codes	Description
C34.0	Malignant neoplasm of main bronchus
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung

C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S)

Portrazza® (Necitumumab) [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 03/2011. Accessed on May 12, 2016 and available at: http://druginserts.com/lib/rx/meds/portrazza/.

NCCN Guidelines Version 3.2017: Non-Small Cell Lung Cancer. Accessed on May 12, 2016 and available at: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp.

Thatcher H, Hirsch FR, Luft AV, et al. Necitumumab Plus Gemcitabine and Cisplatin Versus Gemcitabine and Cisplatin Alone as First-Line Therapy in Patients with Stage IV Squamous Non-Small Cell Lung Cancer (SQUIRE): An Open-Label, Randomized, Controlled Phase 3 Trial. Lancet Oncol. 2015 Jul; 16(7):763-74. Accessed on May 12, 2016 and available at: http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(15)00021-2.pdf.

US Food and Drug Administration (FDA). Center for Biologics Evaluation and Research. Accessed on May 12, 2016 and available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125547s000lbl.pdf.

Portrazza™ web site. Portrazza™ dosing and administration guide. Accessed on May 12, 2016 and available at: http://www.portrazza.com/assets/img/_pdfs/PORTRAZZA-Nurse-Pharmacist-Dosing-Guide.pdf.

Policy History:

Date	Activity
05/12/2016	Initial policy developed
07/01/2016	Provider effective date
12/19/2016	Revisions: Annual Review, updated indications and dosage, and updated references **Criteria Changes**: • The ECOG status criteria has been removed for **NSCLC** indications; • The drug interaction criteria has been updated for NSCLC - OLD CRITERIA *The prescriber provides documentation explaining why the addition of Portrazza to cisplatin and gemcitabine as first line therapy has benefits outweighing the increased risk of toxicity, adverse effects and documented limited efficacy* NEW CRITERIA *Portrazza will be used in combination with gemcitabine and cisplatin for first-line treatment;*
05/17/2017	QI/UM approval
07/01/2017	Provider effective date