Medical Policy:

Portrazza® (necitumumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.159	February 25, 2025	

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

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 800 billable units Day 1 and 8 every 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

Portrazza *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Non-Small Cell Lung Cancer (NSCLC)**
    A. Used as first-line therapy for metastatic disease; **AND**
    B. Used in combination with **BOTH** gemcitabine and cisplatin; **AND**
    C. The member's disease has squamous cell histology; **AND**
    D. Patient is at least 18 years of age

Limitations/Exclusions

Portrazza is not considered medically necessary for when any of the following selection criteria is met:

1. Disease progression while taking Portrazza.
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.

II. RENEWAL CRITERIA

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Tumor response with disease stabilization or reduction of tumor size and spread; **AND**
3. Absence of unacceptable toxicity from the drug. (Examples of unacceptable toxicity include: cardiopulmonary arrest, hypomagnesemia, severe dermatologic toxicity, severe infusion reactions, venous/arterial thromboembolic events, etc.)

Dosage/Administration

Indication	Dose
Squamous NSCLC	800 mg IV Days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion.

Applicable Procedure Codes

Code	Description
J9295	Injection, necitumumab, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
00002-7716-xx	Portrazza 800 mg/50 mL vial

ICD-10 Diagnoses

Code	Description
C33	Malignant neoplasm of trachea
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
C34.2	Malignant neoplasm of middle 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
C34.80	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

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/25/2025	Annual Review: removed Z85.118. Initial Criteria: Reworded the following: "The member has metastatic NSCLC and Portrazza (necitumumab) is being used in combination with gemcitabine and cisplatin; AND" as: " Used as first-line therapy for metastatic disease; AND Used in combination with BOTH gemcitabine and cisplatin; AND" Added: "Patient is at least 18 years of age" Renewal Criteria: Added: "Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiopulmonary arrest, hypomagnesemia, severe dermatologic toxicity, severe infusion reactions, venous/arterial thromboembolic events, etc."
EmblemHealth & ConnectiCare	1/16/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	5/19/2023	Annual Review: Initial Criteria: NSCLC: removed "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, Subsequent therapy for ALK positive tumors AND prior crizotinib therapy"~~ Added: "The member's disease has squamous cell histology"
EmblemHealth & ConnectiCare	09/26/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	07/15/2019	Annual review

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.