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5.21.072

Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 11, 2015
Subject:	Portrazza	**Page:**	1 of 5

Last Review Date: September 19, 2025

Portrazza

Description

Portrazza (necitumumab)

Background
Portrazza (necitumumab) is a medication used in combination with gemcitabine and cisplatin to treat metastatic (advanced) squamous non-small cell lung cancer. Non-small cell lung cancer accounts for about 85 percent of all lung cancers. Among them are the squamous cell carcinoma (also called epidermoid carcinoma), which forms in the lining of the bronchial tubes. Epidermal growth factor receptor (EGFR) is a protein involved in the growth and spread of cancer cells. Portrazza blocks this receptor resulting in decreased tumor growth and cell death. The recommended dose is 800 mg administered as an intravenous infusion over 60 minutes on Days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion. Treatment with Portrazza is to be continued until disease progression or unacceptable toxicity (1).

Regulatory Status
FDA-approved indication: Portrazza is indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer (1).

Limitations of Use: Portrazza is not indicated for the use of non-squamous non-small cell lung cancer (1).

Portrazza label includes a boxed warning citing the risk of cardiopulmonary arrest. Closely monitor serum electrolytes, including serum magnesium, potassium, and calcium, with aggressive replacement when warranted during and after Portrazza administration. Patients

with significant coronary artery disease, myocardial infarction within 6 months, uncontrolled hypertension, and uncontrolled congestive heart failure were not enrolled in the clinical studies. The incremental risk of cardiopulmonary arrest in patients with a history of coronary artery disease, congestive heart failure, or arrhythmias as compared to those without these comorbid conditions is not known (1).

Portrazza also carries a boxed warning on the risk of hypomagnesemia. Monitor patients for hypomagnesemia, hypocalcemia, and hypokalemia prior to each dose of Portrazza during treatment and for at least 8 weeks following completion of treatment. Withhold Portrazza for Grade 3 or 4 electrolyte abnormalities. Subsequent cycles of Portrazza may be administered in these patients once electrolyte abnormalities have improved. Replete electrolytes as medically appropriate (1).

Portrazza can cause fetal harm. Advise females of potential risk to the fetus and to use effective contraception during treatment with Portrazza (1).

Safety and effectiveness of Portrazza in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Portrazza may be considered **medically necessary** if the conditions indicated below are met.

Portrazza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic squamous non-small cell lung cancer

AND ALL of the following:

1. Used in combination with gemcitabine (Gemzar) and cisplatin (Platinol)
2. Prescriber agrees to monitor serum electrolytes, including serum magnesium, potassium, and calcium prior to each dose of Portrazza during treatment and for at least 8 weeks following completion of treatment
3. Prescriber agrees to withhold Portrazza for Grade 3 and 4 electrolyte abnormalities

AND NONE of the following:

1. Non-squamous non-small cell lung cancer

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic squamous non-small cell lung cancer

AND ALL of the following:

1. Used in combination with gemcitabine (Gemzar) and cisplatin (Platinol)
2. Prescriber agrees to monitor serum electrolytes, including serum magnesium, potassium, and calcium prior to each dose of Portrazza during treatment and for at least 8 weeks following completion of treatment
3. Prescriber agrees to withhold Portrazza for Grade 3 and 4 electrolyte abnormalities

AND NONE of the following:

1. Disease progression or unacceptable toxicity
2. Non-squamous non-small cell lung cancer

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Portrazza is an epidermal growth factor receptor (EGFR) inhibitor indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer. Portrazza label includes a box warning citing the risk of cardiopulmonary arrest and hypomagnesemia. Electrolytes should be monitored closely during and after treatment with Portrazza. Portrazza can cause fetal harm and female patients should be advised to use effective contraception during treatment with Portrazza. Safety and effectiveness of Portrazza in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Portrazza while maintaining optimal therapeutic outcomes.

References

1. Portrazza [package insert]. Indianapolis, Indiana: Eli Lilly and Company; November 2015.
2. NCCN Clinical Practice Guidelines Oncology® Non-Small Cell Lung Cancer (Version 7.2025). National Comprehensive Cancer Network, Inc. July 2025. Accessed on July 31, 2025.

Policy History

Date	Action
December 2015	Addition to PA
March 2016	Annual editorial review Policy number changed from 5.04.72 to 5.21.72

June 2016	Annual review and reference update Removal of prescriber agrees to perform a cardiac assessment per SME
September 2016	Annual review
June 2017	Annual editorial review and reference update Addition of age limits to renewal requirements
September 2017	Annual review
June 2018	Annual editorial review
June 2019	Annual review
June 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
September 2023	Annual review and reference update
September 2024	Annual review and reference update
September 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.