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 (1-2).

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).

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

Portrazza label includes a box 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**
Alecensa, Avastin, Cyramza, Gilotrif, Iressa, Keytruda, Opdivo, Tagrisso, Xalkori, Zykdia

**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** for patients 18 years of age and older for the treatment of metastatic squamous non-small cell lung cancer; used in combination with gemcitabine and cisplatin; 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; prescriber agrees to withhold Portrazza for Grade 3 and 4 electrolyte abnormalities; patient does not have non-squamous non-small cell lung cancer.

Portrazza is considered **investigational** in patients under the age of 18 and 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

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

Duration 12 months

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 (1-2).

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

References
**Section:** Prescription Drugs  
**Effective Date:** July 1, 2016  
**Subsection:** Antineoplastic Agents  
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**Subject:** Portrazza  
**Page:** 5 of 5

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

**Keywords**

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 24, 2016 and is effective on July 1, 2016.

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