



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **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).



**BlueCross  
BlueShield**

Federal Employee Program.

## **PORTRAZZA** (necitumumab)

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).

### **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 7.2024). National Comprehensive Cancer Network, Inc. June 2024. Accessed on July 17, 2024.