DESCRIPTION: Necitumumab is a recombinant human IgG1 monoclonal antibody that binds to the human epidermal growth factor receptor (EGFR) and blocks the binding of EGFR to its ligands. Expression and activation of EGFR has been correlated with malignant progression, induction of angiogenesis, and inhibition of apoptosis. Binding of necitumumab induces EGFR internalization and degradation in vitro. In vitro, binding of necitumumab also led to antibody-dependent cellular cytotoxicity (ADCC) in EGFR-expressing cells.

INDICATION(S): Portrazza is indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer.

Recommended dosing 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. Continue PORTRAZZA until disease progression or unacceptable toxicity.

REASONS FOR PA:
- Cost
- Potential for misuse
- Toxicity

CRITERIA for APPROVAL:
1. Patient is an Adult, 18 years of age or greater
2. Patient has been diagnosed with metastatic squamous non-small cell lung cancer
3. Portrazza with be used in combination with gemcitabine and cisplatin
4. Baseline lab work of magnesium, potassium, and calcium have been completed
5. Dosing is 800 mg intravenous on days 1 and 8 of 3 week cycle

REASONS for DENIAL of BENEFIT:
1. Patient has a venous or arterial thromboembolism
2. Patient is currently pregnant, or breastfeeding.
3. Patient does not meet above criteria

RENEWAL CRITERIA:
1. Patient has demonstrated a response to therapy

BENEFIT APPROVAL:
Initial approval for a period of 3 months Renewal approval period: 36 months

References: Portrazza™ (trabectedin) product package insert, Eli Lilly and Company, Indianapolis, IN 46285