Clinical Policy: Necitumumab (Portrazza)

Reference Number: ERX.SPA.282
Effective Date: 08.07.18
Last Review Date: 11.18 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Necitumumab for injection (Portrazza™) is an epidermal growth factor receptor (EGFR) antagonist.

FDA Approved 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 (NSCLC).

Limitation(s) of use: Portrazza is not indicated for treatment of non-squamous NSCLC.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Portrazza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of squamous NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with gemcitabine and cisplatin for first-line treatment of metastatic disease;
5. Dose does not exceed 800 mg on days 1 and 8 of each 3-week cycle.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Portrazza for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 800 mg on days 1 and 8 of each 3-week cycle.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
gemcitabine; cisplatin	Examples of Portrazza/gemcitabine/cisplatin dosing regimens: • Portrazza pivotal trial: o Patients were randomly assigned to gemcitabine 1,250 mg/m^2 IV days 1 and 8, cisplatin 75 mg/m^2 IV day 1 +/- Portrazza 800 mg IV days 1 and 8. • Clinical Pharmacology: o Adults: NSCLC (inoperable, locally advanced, or metastatic): ▪ Gemcitabine 1,000 mg/m^2 IV over 30 minutes followed by cisplatin 100 mg/m^2 IV on day 1, then gemcitabine 1,000 mg/m^2 IV over 30 minutes on days 8 and 15, repeated every 4 weeks. ▪ Alternatively, gemcitabine 1,250 mg/m^2 IV over 30 minutes followed by cisplatin 100 mg/m^2 IV on day 1, then gemcitabine 1,250 mg/m^2 IV over 30 minutes on day 8, repeated every 3 weeks.	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): cardiopulmonary arrest and hypomagnesemia

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Squamous NSCLC	800 mg as an IV infusion over 60 minutes on days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion.	800 mg per infusion

VI. Product Availability

Single-dose vial: 800 mg/50 mL (16 mg/mL)

VII. References

1. Portrazza Prescribing Information. Indianapolis, IN: Eli Lilly and Company; November 2015. Available at http://uspl.lilly.com/portrazza/portrazza.html#pi. Accessed July 2018.
2. National Comprehensive Cancer Network. Non-small cell lung cancer. Version 5.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

4. Thatcher N, Hirsch F, Luft A, et al. Necitumumab plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone as first-1 line therapy in patients with stage IV squamous nonsmall-cell lung cancer (SQUIRE): an open-label, randomised, controlled phase 3 study [published online ahead of print June 1, 2015]. Lancet Oncol. doi: 10.1016/S1470-2045(15)00021-2.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.07.18	11.18

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.