Clinical Policy: Necitumumab (Portrazza)

Reference Number: PA.CP.PHAR.320
Effective Date: 01/18
Last Review Date: 10/30/2019

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness ® clinical policy for necitumumab for injection (Portrazza™).

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
It is the policy of Pennsylvania Health and Wellness ® that Portrazza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of squamous non-small cell lung cancer (NSCLC);
2. Prescribed by or in consultation with an oncologist;
3. Prescribed in combination with gemcitabine and cisplatin for first-line treatment of metastatic disease;
4. Dose does not exceed 800 mg on days 1 and 8 of each 3-week cycle.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets the following:
   a. 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Necitumumab is a recombinant human immunoglobulin G (lgG)1 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. In in vivo studies using xenograft models of human cancer, including non-small cell lung carcinoma, administration of necitumumab to implanted mice resulted in increased antitumor activity in combination with gemcitabine and cisplatin as compared to mice receiving gemcitabine and cisplatin alone.

Formulations:
Portrazza is supplied in single-dose vials as a sterile, preservative-free solution:

- 800 mg/50 mL (16 mg/mL).

Appendices

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
gemcitabine; cisplatin	Examples of Postrazza/gemcitabine/cisplatin dosing regimens: • Portrazza pivotal trial: o Patients were randomly assigned to gemcitabine 1250 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.	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	▪ 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.	

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/Black Box Warnings

- Contraindications: None reported
- Black box warnings: Cardiopulmonary arrest and hypomagnesemia

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9295	Injection, necitumumab, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: no significant changes; added specialist involvement in care, continuation of care added; therapeutics alternatives table added; references reviewed and updated.	08/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	

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 18, 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 18, 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.