Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2021**
Policy Number: PA.CP.PHAR.320	**Effective Date: 01/2018** **Revision Date: 10/2021**
Policy Name: Necitumumab (Portrazza)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Necitumumab (Portrazza)

Reference Number: PA.CP.PHAR.320
Effective Date: 01/18
Last Review Date: 10/2021

Coding Implications
Revision Log

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
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 (must meet all):

1. Diagnosis of squamous non-small cell lung cancer (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. Request meets one of the following (a or b):
   a. Dose does not exceed 800 mg on days 1 and 8 of each 3-week cycle;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

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

II. Continued Approval

A. Non-Small Cell Lung Cancer (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 one of the following (a or b):
   a. New dose does not exceed 800 mg on days 1 and 8 of each 3-week cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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

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 policies – PA.CP.PMN.53

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 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. ▪ 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/Black Box Warnings

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

Appendix D: General Information

- The NCCN NSCLC Panel voted unanimously to delete the Portrazza/cisplatin/gemcitabine regimen from the NCCN Guidelines for patients with metastatic squamous cell NSCLC. This decision reflects the fact that the NCCN NSCLC Panel feels the addition of Portrazza to the regimen is not beneficial based on toxicity, cost, and limited improvement in efficacy when compared with cisplatin/gemcitabine. A phase 3 randomized trial only showed a slight improvement in overall survival (11.5 vs 9.9 months). In addition there were more grade 3 or higher adverse events in patients receiving the Portrazza regimen.

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 June 22, 2021.
2. National Comprehensive Cancer Network. Non-small cell lung cancer. Version 5.2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed June 22, 2021.
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.

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	
4Q 2020 annual review: added general information stating lack of NCCN support for Portrazza based regimen; references reviewed and updated.	10/2020	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	