Clinical Policy: Necitumumab (Portrazza)

Reference Number: LA.PHAR.320
Effective Date: 11.04.23
Last Review Date: 04.04.24 ~~06.25.23~~ Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

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 Louisiana Healthcare Connections® 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. 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

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2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit, 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, 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.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 policy LA.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 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:	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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.	

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 August ~~8, 2022~~10, 2023.
2. National Comprehensive Cancer Network. Non-small cell lung cancer. Version 3.~~2022~~2023. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed August ~~8, 2022~~10, 2023.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; ~~2018~~2023. Available at: ~~http~~https://www.~~clinicalpharmacology-ip~~clinicalkey.com~~/~~/pharmacology/. Accessed August 22, 2023.
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	LDH Approval Date
Converted corporate policy to local policy.	06.25.23	10.05.23
Annual review: no significant changes; references reviewed and updated.	04.04.24	

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Important Reminder

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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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in ~~developingthis~~developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and

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