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Original Effective Date: 03/15/16

Reviewed: 09/11/19

Revised: 11/15/23

Subject: Necitumumab (Portrazza™)

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DESCRIPTION:

Necitumumab (Portrazza), a recombinant human IgG1 monoclonal antibody that binds to the human epidermal growth factor receptor (EGFR), was approved by the U.S. Food and Drug Administration (FDA) in November 2015 treatment of patients with ALK-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. This indication is approved under accelerated approval based on tumor response rate and duration of response [see Clinical Studies (14)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

The efficacy and safety of necitumumab at the recommended dose were demonstrated in an open-label, global, multi-center, 2-arm, randomized trial in 1093 patients with squamous NSCLC (Trial JFCC [SQUIRE]). A 1.6-month improvement in median overall survival (OS) among patients in the gemcitabine/ cisplatin + necitumumab arm compared with those in the gemcitabine/cisplatin arm (HR = 0.842 [0.736, 0.962]; p=0.012) was demonstrated. Necitumumab was associated with a higher rate of adverse events that were grade 3 or higher (72% vs 62%) and serious adverse events (48% versus 38%). Cardiopulmonary arrest and/or sudden death occurred in 3% of patients treated with necitumumab.

National Comprehensive Cancer Network (NCCN) Guidelines for Non-Small Cell Lung Cancer (Version 7.2019) no longer include necitumumab for use in patients with metastatic squamous cell NSCLC. The voting NCCN panel felt the addition of necitumumab to the regimen of cisplatin/gemcitabine was not beneficial based on toxicity, cost, and limited improved in efficacy when compared with cisplatin/gemcitabine alone.

POSITION STATEMENT:

Necitumumab (Portrazza) is associated with a clinically irrelevant benefit and an increased risk of serious adverse events. Use **does not meet the definition of medical necessity** for any indication, including non-small cell lung cancer (NCCN Non-small cell lung cancer guidelines, version 7.2019).

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- 800 mg (absolute dose) as an intravenous infusion over 60 minutes on Days 1 and 8 of each 3-week cycle

Dose Adjustments

- Recommendations for dose modifications due to adverse reactions are provided in FDA-approved Prescribing Information

Drug Availability

- Injection: 800 mg/50 mL (16 mg/mL) solution in a single-dose vial

PRECAUTIONS:

Boxed Warning

- Cardiopulmonary arrest and/or sudden death occurred in 3% of patients treated with necitumumab in combination with gemcitabine and cisplatin
- Hypomagnesemia occurred in 83% of patients receiving necitumumab in combination with gemcitabine and cisplatin, and was severe in 20%

Contraindications

- None

Precautions/Warnings

- Cardiopulmonary Arrest
- Hypomagnesemia
- Venous and Arterial Thromboembolic Events (VTE and ATE)
- Dermatologic Toxicities
- Infusion-Related Reactions
- Increased Toxicity
- Embryo-Fetal Toxicity

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J9295	Injection, necitumumab, 1 mg

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

NCCN Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

1. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2019 [cited 8/28/19]. Available from: http://www.clinicalpharmacology.com/.
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3. DRUGDEX® System [Internet]. Greenwood Village (CO): Thomson Micromedex; Updated periodically [cited 8/28/19]. Available from: http://www.thomsonhc.com/.

4. Eli Lilly. Necitumumab (Portrazza) solution. 2019 [cited 8/28/19]. In: DailyMed [Internet]. Bethesda (MD): National Library of Medicine. Available from: http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e81b4a7-b971-45e1-9c31-29cea8c87ce7/.
5. National Comprehensive Cancer Network®. NCCN clinical practice guidelines in oncology (NCCN Guidelines®). Non-small cell lung cancer, v. 7.2019 [cited 8/28/19]. Available from: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.
6. NCCN Drugs & Biologics Compendium [Internet]. Fort Washington (PA): National Comprehensive Cancer Network; 2018 [cited 8/28/19]. Available from: http://www.nccn.org/professionals/drug_compendium/content/contents.asp/.
7. Orphan Drug Designations and Approval [Internet]. Silver Spring (MD): US Food and Drug Administration; 2015 [cited 8/28/19]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm/.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 9/11/19.

GUIDELINE UPDATE INFORMATION:

03/15/16	New Medical Coverage Guideline.
04/01/16	Revision to guideline consisting of adding code C9475.
05/15/16	Revision to program exceptions to add LCD L33915.
01/01/17	Revision: added HCPCS code J9295.
10/15/17	Review and revision to guideline, consisting of updating position statement, coding, references.
10/15/18	Review and revision to guideline, consisting of updating position statement, coding, references.
10/15/19	Review and revision to guideline, consisting of updating position statement, references; changed to NLR.
11/15/23	Revision: removed reference to retired LCD L33915.