Necitumumab (Portrazza®)

NDC CODE(S) 00002-7716-XX PORTRAZZA 800MG/50ML Solution (LILLY)

DESCRIPTION
Necitumumab is a recombinant monoclonal antibody which binds to the human epidermal growth factor receptor (EGFR) and blocks it binding to its ligands. It is considered to be an epidermal growth factor receptor (EGFR) antagonist, causing the eventual destruction of cells upon whose growth and proliferation depend on the activity of EGFR, such as those in the progression of lung cancer.
POLICY

POLICY

- Necitumumab for the treatment of non-small cell lung cancer (NSCLC) is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Necitumumab for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient must be at least 18 years old; **AND**

Non-Small Cell Lung Cancer (NSCLC)

- Patient must have metastatic disease; **AND**
- Disease must have squamous cell histology; **AND**
- Must be used in combination with BOTH gemcitabine and cisplatin; **AND**
- Patient must have a performance status of 0-2; **AND**
- Must be used as first-line therapy

RENEWAL CRITERIA

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in the Initial Approval Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiopulmonary arrest, hypomagnesemia, severe dermatologic toxicity, severe infusion reactions and venous/arterial thromboembolic events.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Squamous NSCLC	Administer 800 mg intravenously on Days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion. Give until disease progression or unacceptable toxicity.

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed

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DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- 800 billable units Day 1 and 8 every 21 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Portrazza [package insert]. Indianapolis, IN; Eli Lilly and Company; November 2015. Accessed March 2021.
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Non-Small Cell Lung Cancer, Version 4.2021. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
3. Thatcher N, Hirsch FR, Luft AV, et al SQUIRE Investigators. Necitumumab plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone as first-line therapy in patients with stage IV squamous non-small-cell lung cancer (SQUIRE): an open-label, randomised, controlled phase 3 trial. Lancet Oncol. 2015;16(7):763. Epub 2015 Jun 1.
4. Paz-Ares L, Mezger J, Ciuleanu TE, et al INSPIRE Investigators. Necitumumab plus pemetrexed and cisplatin as first-line therapy in patients with stage IV non-squamous non-small-cell lung cancer (INSPIRE): an open-label, randomised, controlled phase 3 study. Lancet Oncol. 2015;16(3):328. Epub 2015 Feb 18.
5. Lexi-Comp Online. (2018). AHFS DI. *Necitumumab*. Retrieved January 3, 2019 from Lexi-Comp Online with AHFS.
6. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2019, December). *Necitumumab*. Retrieved April 7, 2020 from MICROMEDEX Healthcare Series.

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Policy

Medical Policy Manual **Approved Reformatted: Do Not Implement until 8/31/21**

EFFECTIVE DATE 8/31/2021

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