POLICY: Oncology – Portrazza® (necitumumab injection for intravenous use – Eli Lilly)

APPROVAL DATE: 01/03/2019

OVERVIEW

Portrazza is indicated in combination with gemcitabine and cisplatin for the first-line treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC).[1] It has a limitation of use noted that it is not indicated for the treatment of non-squamous NSCLC.

The recommended dose of Portrazza is 800 mg as an intravenous (IV) infusion over 60 minutes on Days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion. Portrazza is continued until disease progression or unacceptable toxicity. Dose modifications for infusion-related reactions and dermatologic toxicity are noted in the prescribing information.

Guidelines

The National Comprehensive Cancer Network (NCCN) NSCLC cancer guidelines (version 2.2019) notes that Portrazza/cisplatin/gemcitabine in the first-line setting is not used at NCCN member institutions due to the efficacy and safety of this agent compared to the efficacy/safety of other available agents.[2]

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Portrazza. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Portrazza as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Portrazza to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Portrazza is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** The patient has metastatic squamous NSCLC; AND
   - **B)** Portrazza will be used in combination with chemotherapy (e.g., gemcitabine, cisplatin); AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve Portrazza 800 mg administered on Days 1 and 8 of each 3-week cycle.

   Duration of Therapy: Extended approvals are allowed if the patient continues to meet the criteria and dosing (see above).
   - Treatment may continue until disease progression or unacceptable toxicity.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

1. **Other Indications.** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.

REFERENCES

1. Portrazza® Intravenous Infusion [prescribing information]. Indianapolis, IN: Eli Lilly and Company; November 2015.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 2.2019 – November 21, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on December 31, 2018.

HISTORY

Type of Revision	Summary of Changes*	Approval Date
New policy	--	01/03/2019