Clinical Policy: Necitumumab (Portrazza)
Reference Number: CP.PHAR.320
Effective Date: 03.01.17
Last Review Date: 11.19
Line of Business: Medicaid, HIM-Medical Benefit

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

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 health plans affiliated with Centene Corporation® 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
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.
II. Continued Therapy
   A. Non-Small Cell Lung Cancer (must meet all):
      1. Currently receiving medication via Centene 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. Currently receiving medication via Centene benefit and documentation supports
         positive response to therapy.
         Approval duration: Duration of request or 6 months (whichever is less); or
      2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT
         specifically listed under section III (Diagnoses/Indications for which coverage is
         NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 –
      CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents.

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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>gemcitabine; cisplatin</td>
<td>Examples of Portrazza/gemcitabine/cisplatin dosing regimens:</td>
<td>Varies</td>
</tr>
<tr>
<td></td>
<td>• Portrazza pivotal trial:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Patients were randomly assigned to gemcitabine</td>
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<tr>
<td></td>
<td>1250 mg/m² IV days 1 and 8, cisplatin 75 mg/m² IV day 1 +/- Portrazza 800 mg IV days 1 and 8.</td>
<td></td>
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<tr>
<td></td>
<td>• Clinical Pharmacology:</td>
<td></td>
</tr>
</tbody>
</table>
Drug Name | Dosing Regimen | Dose Limit/Maximum Dose
---|---|---
| | | 
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| | | 

Adults: NSCLC (inoperable, locally advanced, or metastatic):
- Gemcitabine 1,000 mg/m² IV over 30 minutes followed by cisplatin 100 mg/m² IV on day 1, then gemcitabine 1,000 mg/m² IV over 30 minutes on days 8 and 15, repeated every 4 weeks.
- Alternatively, gemcitabine 1,250 mg/m² IV over 30 minutes followed by cisplatin 100 mg/m² IV on day 1, then gemcitabine 1,250 mg/m² 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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Squamous NSCLC</td>
<td>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.</td>
<td>800 mg per infusion</td>
</tr>
</tbody>
</table>

VI. Product Availability
- Single-dose vial: 800 mg/50 mL (16 mg/mL)

VII. References


**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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J9295</td>
<td>Injection, necitumumab, 1 mg</td>
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**Reviews, Revisions, and Approvals**

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>01.17</td>
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**Important Reminder**

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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