

Clinical Policy Title:	necitumumab
Policy Number:	RxA.453
Drug(s) Applied:	Portrazza™
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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.

*NCCN and NSCLC Panel do not recommend the necitumumab/cisplatin/gemcitabine regimen for patients with metastatic squamous cell NSCLC.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy; 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

Commercial: 12 months

Medicaid: 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

References

1. National Comprehensive Cancer Network. Non-small cell lung cancer. Version 3.2023. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed April 25, 2023.
2. 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/S14702045(15)00021-2. Available at: <https://pubmed.ncbi.nlm.nih.gov/26045340/>. Accessed April 25, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to “All lines of business” 3. Continued therapy criteria II.A.1: rephrased to “Currently receiving medication that has been authorized by RxAdvance..” 4. Added Commercial, Medicaid & HIM approval duration. 5. References were updated. 	06/17/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A and Continued Therapy Criteria II.A: Updated to add verbiage *NCCN and NSCLC Panel do not recommend the necitumumab/cisplatin/gemcitabine regimen for patients with metastatic squamous cell NSCLC. 2. References were reviewed and updated. 	03/30/2022	07/18/2022
Policy was reviewed: <ol style="list-style-type: none"> 1. Continued Therapy Criteria II.A: Approval Duration for commercial and Medicaid updated from 6 months to 12 months. 2. References were reviewed and updated. 	04/25/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023