Clinical Policy: Penpulimab-kcqx

Reference Number: CP.PHAR.732
Effective Date: 09.01.25
Last Review Date: 08.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Penpulimab-kcqx is a programmed death receptor-1 (PD-1)-blocking antibody.

FDA Approved Indication(s)

Penpulimab-kcqx is indicated:

- In combination with either cisplatin or carboplatin and gemcitabine for the first-line treatment of adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC)
- As a single agent for the treatment of adults with metastatic non-keratinizing NPC with disease progression on or after a platinum-based chemotherapy and at least one other prior line of therapy

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 penpulimab-kcqx is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Keratinizing Nasopharyngeal Carcinoma (must meet all)**:**

1. Diagnosis of non-keratinizing NPC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥18 years;
4. Disease is recurrent or metastatic;
5. Penpulimab-kcqx is prescribed in one of the following ways (a or b):
   a. In combination with cisplatin or carboplatin and gemcitabine;
   b. As a single agent for disease that has progressed on or after both of the following (i and ii):
      i. Platinum-containing chemotherapy (see *Appendix B*);
      ii. At least one other prior line of therapy (see *Appendix B*);
6. Member has not received prior treatment with an anti-PD-(L)1 antibody;
7. Request meets one of the following (a, b, or c):*
   a. In combination with cisplatin or carboplatin and gemcitabine: Dose does not exceed 200 mg every three weeks;
   b. As a single agent: Dose does not exceed 200 mg every two weeks;

c. 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.*

Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Non-Keratinizing Nasopharyngeal Carcinoma (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving penpulimab-kcqx 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, b, or c):*
   a. In combination with cisplatin or carboplatin and gemcitabine: New dose does not exceed 200 mg every three weeks for up to total maximum of 24 months;
   b. As a single agent: New dose does not exceed 200 mg every two weeks for up to total maximum of 24 months;
   c. 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:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
NPC: nasopharyngeal carcinoma
PD-1: programmed death receptor-1

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin, cetuximab	Varies	Varies
cisplatin, gemcitabine	Varies	Varies
cisplatin, gemcitabine, Loqtorzi®	Varies	Varies
cisplatin, gemcitabine, Tevimbra™	Varies	Varies
cisplatin, 5-FU	Varies	Varies
cisplatin or carboplatin, docetaxel, or paclitaxel	Varies	Varies
docetaxel, cisplatin, 5-FU	Varies	Varies
gemcitabine, carboplatin	Varies	Varies
Loqtorzi	Varies	Varies
Tevimbra	Varies	Varies

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/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
First-line treatment of recurrent or metastatic NPC	In combination with cisplatin or carboplatin and gemcitabine: 200 mg IV every three weeks until disease progression or a maximum of 24 months	200 mg every three weeks
Previously treated recurrent or metastatic NPC	As a single agent: 200 mg IV every two weeks until disease progression or a maximum of 24 months	200 mg every two weeks

VI. Product Availability

Solution in single-dose vial: 100 mg/10 mL

VII. References

1. Penpulimab-kcqx Prescribing Information. Guangdong, China: Akeso Biopharma Co., Ltd.; April 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761258Orig1s000correctedlbl.pdf . Accessed May 13, 2025.
2. National Comprehensive Cancer Network. Head and Neck Cancers Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed May 13, 2025.
3. A Study of Anti-PD-1 AK105 in Patients With Metastatic Nasopharyngeal Carcinoma. ClinicalTrials.gov identifier: NCT03866967. Updated February 27, 2025. Available at: https://clinicaltrials.gov/study/NCT03866967. Accessed May 13, 2025.
4. A Study of Penpulimab (AK105) in the First-line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma. ClinicalTrials.gov identifier: NCT04974398. Updated April 13, 2025. Available at: https://clinicaltrials.gov/study/NCT04974398. Accessed May 13, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.13.25	08.25

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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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