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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 06/11/2026

Penpulimab-kcqx

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Treatment must follow the FDA approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation
 - i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation
 - b. Prescribed by or in consultation with an oncologist or hematologist
 - c. No prior failure of a programmed death receptor-1 (PD-1) inhibitor
 - d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant
 - e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Treatment continued until unacceptable toxicity, disease progression, or 24 months of therapy have been given

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Penpulimab-kcqx is a programmed death receptor-1 (PD-1)–blocking antibody 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 platinum-based chemotherapy and at least one other prior line of therapy
- The National Comprehensive Cancer Network (NCCN) guidelines category 1 and 2A recommendations are based on uniform NCCN consensus that the recommendations are appropriate. Treatment regimens have been studied and shown to be efficacious when administered as listed in the guidelines. Category 2B and 3 recommendations do not have a high level of evidence to support use and also do not have a uniform consensus from the NCCN panel that the recommendations are appropriate.
- There are no studies to support use of penpulimab-kcqx following failure. NCCN treatment guidelines also do not recommend use of PD-L1 checkpoint inhibitors following a previous failure.
- Penpulimab-kcqx has not been studied in patients on chronic immunosuppressant therapy and therefore, should not be used in patients on chronic immunosuppressants.

References:

1. Penpulimab-kcqx [prescribing information]. Zhonghan, Guangdong, China: Akeso Biopharma Co., Ltd.; April 2025.
2. Clinicaltrials.gov. A study of penpulimab (AK105) in the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma (NCT04974398). Available at: <https://clinicaltrials.gov/study/NCT04974398>. Accessed on April 28, 2025.
3. Clinicaltrials.gov. A study of anti-PD-1 AK105 in patients with metastatic nasopharyngeal carcinoma (NCT03866967). Available at: <https://clinicaltrials.gov/study/NCT03866967>. Accessed on April 28, 2025.
4. National Comprehensive Cancer Network. Head and neck cancers (Version 1.2026). 2025 Dec 8. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed on April 14, 2026.

Policy History												
#	Date	Change Description										
1.1	Effective Date: 06/11/2026	Annual review of criteria was performed, no changes were made										
1.0	Effective Date: 06/05/2025	New Policy<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

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