

# Penpulimab-KCQX (penpulimab-kcqx) (Intravenous)

Document Number: IC-0795

**Last Review Date: 06/05/2025**

**Date of Origin: 06/05/2025**

**Dates Reviewed: 06/2025**

## I. Length of Authorization <sup>Δ 1</sup>

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter (unless otherwise specified).
  - Head and Neck Cancers can be authorized up to a maximum of 24 months (35 or 52 total doses based on indication).

## II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

- 200 mg every 2 weeks

## III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

**Universal Criteria <sup>1,2</sup>**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy <sup>Δ</sup>; **AND**

**Nasopharyngeal carcinoma (NPC) † Φ <sup>1-5</sup>**

- Patient has non-keratinizing disease; **AND**
  - Used as first-line therapy; **AND**
    - Patient has metastatic OR recurrent disease; **AND**
    - Used in combination with either cisplatin or carboplatin and gemcitabine; **OR**
  - Used as subsequent therapy; **AND**
    - Patient has recurrent metastatic disease; **AND**
    - Used as single-agent therapy; **AND**
    - Patient experienced disease progression on or after a platinum-containing chemotherapy regimen and at least one other prior line of therapy

❖ *If confirmed using an FDA approved assay – <http://www.fda.gov/CompanionDiagnostics>*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

#### IV. Renewal Criteria <sup>Δ 1,4,5,9</sup>

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe immune-mediated adverse reactions (e.g., pneumonitis, hepatotoxicity and hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

<sup>Δ</sup> Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy beyond the 24-month limit without interruption or discontinuation.

#### V. Dosage/Administration <sup>Δ 1,9-13</sup>

Indication	Dose
Head and Neck Cancers	<u>Combination therapy</u> Administer 200 mg intravenously every three weeks until disease progression or unacceptable toxicity, or up to 24 months.
	<u>Single-agent therapy</u> Administer 200 mg intravenously every two weeks until disease progression or unacceptable toxicity, or up to 24 months.

#### VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drugs

NDC:

- Penpulimab-kcqx 100 mg/10 mL (10 mg/mL) single-dose vial: 83654-0105-xx

## VII. References

1. Penpulimab-kcqx [package insert]. Guangdong, China; Akeso Biopharma Co., Ltd.; April 2025. Accessed April 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) penpulimab. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Head and Neck Cancers. Version 2.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2025.
4. Chaosu Hu, Xiaozhong Chen, Tingting Xu, et al; Abstract CT011: Penpulimab versus placebo in combination with chemotherapy as first-line treatment for recurrent or metastatic nasopharyngeal carcinoma: A global, multicenter, randomized, double-blind, phase 3 trial (AK105-304). Cancer Res 15 April 2025; 85 (8\_Supplement\_2): CT011. <https://doi.org/10.1158/1538-7445.AM2025-CT011>
5. Huang Z, Pang X, Zhong T, et al. Penpulimab, an Fc-Engineered IgG1 Anti-PD-1 Antibody, With Improved Efficacy and Low Incidence of Immune-Related Adverse Events. Front Immunol. 2022 Jun 27;13:924542. doi: 10.3389/fimmu.2022.924542. eCollection 2022.
6. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2018 Mar;14(3):e130-e136.
7. Hematology/Oncology Pharmacy Association (2019). Intravenous Cancer Drug Waste Issue Brief. Retrieved from [https://www.hoparx.org/documents/65/HOPA\\_Drug\\_Waste\\_Issue\\_Brief\\_-\\_Updated\\_01.19.22\\_FINAL.pdf](https://www.hoparx.org/documents/65/HOPA_Drug_Waste_Issue_Brief_-_Updated_01.19.22_FINAL.pdf)
8. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. BMJ. 2016 Feb 29;352:i788.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx

ICD-10	ICD-10 Description
C11.9	Malignant neoplasm of nasopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C30.0	Malignant neoplasm of nasal cavity
D37.05	Neoplasm of uncertain behavior of pharynx
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC