Penpulimab-KCQX (penpulimab-kcqx)
(Intravenous)

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I. Length of Authorization Δ [1]

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter up to a maximum of 24 months (35 or 52 total doses based on regimen).

II. Dosing Limits

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

- 200 mg every 2 weeks

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

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

Universal Criteria [1,2]

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified Δ; **AND**

Head and Neck Cancers † ‡ Φ [1-5]

- Patient has non-keratinizing disease; **AND**
  - Patient has Cancer of the Nasopharynx; **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**
      - Used as single-agent therapy †; **AND**
        - Patient has recurrent metastatic disease; **AND**

- Patient experienced disease progression on or after a platinum-containing chemotherapy regimen and at least one other prior line of therapy; **OR**
- Used in combination with either cisplatin or carboplatin and gemcitabine (if not previously used); **AND**
- Patient has metastatic disease; **OR**

- Patient has Very Advanced Head and Neck Cancer*; **AND**
  - Patient has nasopharyngeal cancer; **AND**
  - Patient has a performance status 0-1; **AND**
  - Used as subsequent therapy in combination with either cisplatin or carboplatin and gemcitabine (if not previously used); **AND**
    - Used for one of the following:
      - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
      - Unresectable second primary with prior RT; **OR**
      - Unresectable persistent disease with prior RT; **OR**
      - Recurrent/persistent disease with distant metastases

***** *Very Advanced Head and Neck Cancer includes: Newly diagnosed (M0) locally advanced T4b, N0-3 disease; newly diagnosed unresectable regional nodal disease; newly diagnosed disease and unfit for surgery; metastatic disease at initial presentation (M1); or recurrent or persistent disease.*

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

IV. Renewal Criteria [Δ 1,4,5,9]

Prior authorization validity 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.

[Δ] 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.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.

V. Dosage/Administration Δ [1,9-13]

Indication	Dose
Head and Neck Cancers	Combination therapy Administer 200 mg intravenously every three weeks until disease progression or unacceptable toxicity, or up to 24 months. Single-agent therapy 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 September 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) penpulimab-kcqx. 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 September 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Head and Neck Cancers. Version 5.2025. 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 September 2025.

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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). Updated February 2024. Intravenous Cancer Drug Waste Issue Brief. Retrieved from https://www.hoparx.org/documents/287/HOPA_Drug_Waste_Issue_Brief_-_Updated_02.22.24.pdf
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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
C79.89	Secondary malignant neoplasm of other specified sites
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