

Medical Drug Clinical Criteria

Subject: Penpulimab-kcqx

Document #: CC-0285

Status: New

Publish Date: 07/08/2025

Last Review Date: 06/09/2025

Table of Contents

[Overview](#)

[Coding](#)

[References](#)

[Clinical Criteria](#)

[Document History](#)

Overview

This document addresses the use of penpulimab-kcqx. Penpulimab is a PD-1 blocking antibody FDA indicated for use in combination with either cisplatin or carboplatin and gemcitabine for first-line treatment in adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma. It is also FDA indicated as a single agent for use in adults with metastatic non-keratinizing NPC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

Definitions and Measures

Adenocarcinoma: Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.

Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

Disease Progression: Cancer that continues to grow or spread.

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte-associated antigen (CTLA)-4/B7-1/B7-2 (NCI, 2018).

Line of Therapy:

- **First-line therapy:** The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- **Second-line therapy:** Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.

- **Third-line therapy:** Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Maintenance therapy: Designed to maintain a condition to prevent a relapse.

Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Mutation: A permanent, transmissible change in genetic material.

Neoadjuvant therapy: Treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy. It is a type of induction therapy.

One line of therapy: Single line of therapy.

Partial response (PR): A decrease in the size of a tumor, or in the amount of cancer in the body, resulting from treatment; also called partial remission.

Primary refractory disease: Cancer that does not respond at the beginning of treatment; may also be called resistant disease.

Primary treatment: The first treatment given for a disease. It is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation. Also called first-line therapy, induction therapy, and primary therapy.

Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Stable disease: Cancer that is not decreasing or increasing in extent or severity.

Targeted biologic agent: A newer type of drug developed specifically to target genetic changes in cells that cause cancer. It works differently than standard chemotherapy drugs, often with different side effects.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Penpulimab-kcqx Injection

Requests for Penpulimab-kcqx Injection may be approved if the following criteria are met:

- I. Individual has a diagnosis of nasopharyngeal carcinoma (NPC); **AND**
- II. Individual is using in one of the following ways:
 - A. In combination with either cisplatin or carboplatin and gemcitabine for first-line treatment in recurrent or metastatic nonkeratinizing NPC; **OR**
 - B. As a single agent in nonkeratinizing NPC with disease progression on or after platinum-based chemotherapy and at least one prior line of therapy.

Requests for Penpulimab-KcqX Injection may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as penpulimab-kcgx]
J9999	Not otherwise classified, antineoplastic drugs [when specified as penpulimab-kcgx]

ICD-10 Diagnosis

All diagnosis pend.

Document History

New: 06/09/2025

Document History:

- 06/09/2025 – Select Review: New document for Penpulimab-kcqX PA. Coding Reviewed: Added HCPCS NOC C9399, J9999, and all diagnosis pend for penpulimab-kcgx.

References

1. Clinicaltrials.gov. National Library of Medicine. Available at: <https://clinicaltrials.gov/>. Accessed on May 22, 2025.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: May 22, 2025.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on May 22, 2025.
 - a. Head and Neck Cancer. V2.2025. Revised January 17, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association