Reference number(s)
6960-A

Standard Medicare Part B Management penpulimab-kcqx

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Penpulimab-kcqx	penpulimab-kcqx

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Nasopharyngeal Carcinoma (NPC)

- 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 NPC.
- Penpulimab-kcqx is indicated as a single agent for the treatment of adults with metastatic non-keratinizing NPC and disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

Compendial Uses[2]

- Appendiceal neoplasms and cancers including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified

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All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Exclusions

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 therapy.

Documentation

The following documentation must be available, upon request, for all submissions:

- Documentation of laboratory report confirming MSI-H, mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumor status with tumor mutational burden (TMB), where applicable.

Coverage Criteria

Nasopharyngeal Carcinoma (NPC)[1]

Authorization of 12 months may be granted for the treatment of non-keratinizing nasopharyngeal carcinoma when either of the following criteria is met:

- The requested medication will be used as first-line treatment of recurrent or metastatic disease in combination with either cisplatin or carboplatin and gemcitabine for six cycles and then as a single agent.
- The requested medication will be used as a single agent for the treatment of metastatic disease with progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

Appendiceal Neoplasms and Cancer[2]

Authorization of 12 months may be granted for the treatment of appendiceal neoplasms and cancers including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified when used as a single agent for deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H), or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., tumor mutational burden [TMB] >50 mut/Mb).

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Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months (up to 24 months total) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this document were created after examining the following resources:

- The prescribing information for penpulimab-kcqx.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Appendiceal Neoplasms and Cancers
- NCCN Guideline: Head and Neck Cancers

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for penpulimab-kcqx are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using penpulimab-kcqx to treat appendiceal neoplasms and cancers can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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References

1. penpulimab-kcqx [package insert]. Zhongshan, Guangdong, China: Akeso Biopharma Co., Ltd.; April 2025.
2. The NCCN Drugs & Biologics Compendium© © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed November 12, 2025.

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