

Specialty Guideline 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 Indications¹

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 Uses²

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

All other indications are considered experimental/investigational and not medically necessary.

Exclusions

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- 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 6 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 Cancer²

Authorization of 6 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).

Continuation of Therapy

Authorization of 6 months (up to 24 months total) may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. penpulimab-kcq [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.