

Specialty Guideline Management

Ziihera

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
Ziihera	zanidatamab-hrii

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 Indication¹

HER2-positive Biliary Tract Cancer

Ziihera is indicated for the treatment of adults with previously treated, unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive immunohistochemistry (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test.

Compendial Use²

- HER2-positive biliary tract cancer

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status (e.g., immunohistochemistry [IHC] score).

Coverage Criteria

Biliary Tract Cancer^{1,2}

Authorization of 12 months may be granted for subsequent treatment of unresectable or resected gross residual (R2) disease or metastatic HER2-positive (IHC 3+) biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer) when used as a single agent.

Continuation Of Therapy

Authorization of 12 months 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. Ziihera [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed July 15, 2025.