VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Ziihera Prior Authorization Policy
- Ziihera® (zanidatamab-hrii intravenous infusion – Jazz)

REVIEW DATE: 12/04/2024

OVERVIEW
Ziihera, a bispecific human epidermal growth factor receptor 2 (HER2)-directed antibody, is indicated for the treatment of previously treated, unresectable or metastatic HER2-positive (immunohistochemistry [IHC] 3+) **biliary tract cancer**, as detected by an FDA-approved test in adults.[1]

Guidelines
The National Comprehensive Cancer Network (NCCN) biliary tract cancers (version 5.2024 – November 27, 2024) guidelines recommended Ziihera as "Useful in Certain Circumstances" for the subsequent treatment of unresectable, resected gross residual, or metastatic gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma that is HER2-positive (IHC3+) [category 2A].[2,3]

Safety
Ziihera has a Boxed Warning for embryo-fetal toxicity.[1]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Ziihera. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ziihera as well as the monitoring required for adverse events and long-term efficacy, approval requires Ziihera to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Ziihera is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Biliary Tract Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has ONE of the following (i, ii, or iii):
     - **i.** Gallbladder cancer; OR
     - **ii.** Intrahepatic cholangiocarcinoma; OR
     - **iii.** Extrahepatic cholangiocarcinoma; AND
   - **C)** Patient has unresectable, resected gross residual, or metastatic disease; AND
   - **D)** The tumor is human epidermal growth factor receptor 2 (HER2) positive with immunohistochemistry score of 3+ (IHC3+) as determined by an approved test; AND
   - **E)** The medication is used for subsequent therapy; AND

F) The medication is used as a single agent; AND
G) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ziihera is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ziihera® intravenous infusion [prescribing information]. Palo Alto, CA: Jazz; November 2024.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 27, 2024. Search term: zanidatamab.
3. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 5.2024 – November 27, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 27, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/04/2024