Zanidatamab-hrii (ZIHERA)
Criteria for Use
March 2026

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive zanidatamab.

- ☐ Left Ventricular Ejection Fraction < 50%
- ☐ Pregnancy
- ☐ Lactating

Inclusion Criteria

All of the following criteria must be met.

- ☐ Care provided by a VA or VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group Performance Status 0 - 2
- ☐ Unresectable or metastatic biliary tract cancer
- ☐ Progressive disease on at least one prior chemotherapy regimen
- ☐ HER2-positive, IHC 3+
- ☐ Patient is not a candidate for fam-trastuzumab deruxtecan, trastuzumab/tucatinib or trastuzumab/pertuzumab

Additional Inclusion Criteria

- ☐ For females who can become pregnant: Pregnancy should be excluded prior to receiving zanidatamab.
- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 4 months after stopping treatment

Other Justification

- ☐ _____

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