

Oncology Immunotherapies
Ziihera (zanidatamab-hrii)
Effective 05/12/2025

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Ziihera (zanidatamab-hrii) is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC)
2. Member is ≥18 years of age
3. Prescriber is an oncologist
4. Member's current weight
5. Inadequate response or adverse reaction to ONE prior gemcitabine-containing regimen for BTC
6. Appropriate dosing

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months

References

1. Ziihera® (zanidatamab-hrii) [package insert]. Palo Alto (CA): Jazz Pharmaceuticals, Inc.; 2024 Nov.

2. NCCN. NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancer Version 6.2024 [guideline on the internet]. 2025 Jan 10 [cited 2025 Jan 16]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf

Review History

04/09/25 – Created for P&T. Adopted MH criteria. Ziihera will be managed through medical benefit only with PA. Effective 5/12/25

