Ziihera

Ziihera (Zanidatamab-hrii) J9276

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ Extensive-Stage Small Cell Lung Cancer (ES-SCLC) – Relapsed or Refractory

- ☐ Patient is 18 years or older
- ☐ Confirmed diagnosis of extensive-stage small cell lung cancer
- ☐ Patient has received at least one prior line of platinum-based chemotherapy
- ☐ Patient has relapsed or refractory disease following most recent therapy
- ☐ ECOG performance status 0-1
- ☐ No active untreated CNS metastases (treated and stable CNS metastases permitted)
- ☐ No history of pneumonitis or interstitial lung disease requiring steroids
- ☐ Prescribed by or in consultation with oncologist
- ☐ Patient is enrolled in and will be monitored through Ziihera REMS program (if applicable)

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ Patient continues to meet initial approval criteria

☐ No evidence of disease progression

☐ No unacceptable toxicity requiring discontinuation (e.g., severe cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome)

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Ziihera Prior Authorization

Drug Name(s):

ZIIHERA **ZANIDATAMAB-HRII**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Oncologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Ziihera

- Biliary tract cancer, Unresectable or metastatic, previously treated, HER2-positive (IHC 3+)

Off-Label Uses:

N/A

Age Restrictions:

Safety and efficacy of zanidatamab-hrii have not been established in pediatric patients

Other Clinical Consideration:

- Warning: Embryo-Fetal Toxicity
- Exposure to Zanidatamab-Hrii during pregnancy can cause embryofetal harm. Advise patients of the risk and need for effective contraception

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Ziihera&SearchFilter=filterNone#