ZIIHERA®
(zanidatamab-hrii)
50 mg/ml Injection for IV

The FIRST and ONLY dual HER2-targeted bispecific antibody + tislelizumab + CT regimen FDA-approved for 1L treatment of adult patients with HER2+ advanced GEA, irrespective of PD-L1 status[1]

ZIIHERA GEA Reimbursement Toolkit

For more information, click here or contact your Jazz Pharmaceuticals Field Access Navigator:

Name: _____ **Phone:** _____

Email: _____

INDICATIONS

ZIIHERA (zanidatamab-hrii) 50 mg/mL is indicated:

- In combination with fluoropyrimidine- and platinum-containing chemotherapy and tislelizumab-jsgr, as first-line treatment for adult patients with HER2-positive (IHC 3+ or IHC 2+/ISH+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma, as detected by an FDA-authorized test.
- In combination with fluoropyrimidine- and platinum-containing chemotherapy, as first-line treatment for adult patients with HER2-positive (IHC 3+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma, as detected by an FDA-authorized test.

IMPORTANT SAFETY INFORMATION

WARNING: DIARRHEA and EMBRYO-FETAL TOXICITY

- **ZIIHERA, in combination with fluoropyrimidine- and platinum-containing chemotherapy, with or without tislelizumab-jsgr, can cause severe diarrhea, including life threatening and fatal cases. Use antidiarrheal prophylaxis during the first cycle when ZIIHERA is given in combination with these drugs. Manage with antidiarrheals and supportive measures as clinically indicated. Interrupt, reduce the dose or discontinue ZIIHERA based on severity.**
- **Embryo-Fetal Toxicity: Exposure to ZIIHERA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.**

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

Please note: Jazz Pharmaceuticals does not guarantee payment or coverage for any product or service. All billing and coding information should be verified by the provider for each patient prior to treatment. Providers are responsible for contacting payers directly to confirm requirements and obtain any updated guidance. It is also the provider's responsibility to determine the appropriate healthcare setting and submit accurate claims for all products and services rendered. In addition, all forms, checklists and resources provided within this toolkit are intended as examples.

1L=first-line; CT=chemotherapy; FDA=Food and Drug Administration; GEA=gastroesophageal adenocarcinoma; HER2+=human epidermal growth factor receptor 2-positive; PD-L1=programmed death-ligand 1.

Understanding and using the ZIIHERA Reimbursement Toolkit

This resource is designed to support office staff with resources and information related to billing, coding, coverage, and reimbursement for ZIIHERA.

It includes sample checklists and template letters, details about patient support services offered by Jazz Pharmaceuticals, frequently asked questions about coverage and reimbursement, and contact information for key stakeholders who can assist with medical, access, and patient support topics.

When using this resource, it may be helpful to consider where your patients are in their treatment journey, as resources in this guide are tailored for each step. The **Field Access Navigator (FAN)** serves as a key contact for additional information on patient access to ZIIHERA and available JazzCares support services.

Sample prescription pathway

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Initial prescription benefits verification

See sample checklist on page 5

Benefits investigation

- Investigates benefits so patients understand their insurance coverage
- Identifies applicable copay and other OOP costs

PA (if required) claim sent to payer

See sample checklist on page 5

PA support

- Provides information on PA process, outcomes, and next steps

PA denial and appeals

See sample LMN on page 7 and sample LOA on page 9

Appeals support

- Offers support on the appeals process following a denied PA, precertification, and/or claim

Some patients will be approved without a denial

Approval and treatment

See sample claim forms pages 11-12 and billing and coding info pages 13-14

Reimbursement support

- Answers billing, coding, and reimbursement-related questions

Drug sent to patient

See specialty distributor and GPO info page 15

Financial assistance programs[a]

- Patient Assistance Program[b]
- Savings card

For more information on JazzCares offerings and guidance on how to enroll, see patient support services on page 16

[a]Insurance coverage and plans may vary. JazzCares provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional.

[b]Subject to financial and residency eligibility criteria. Terms and conditions apply.

GPO=group purchasing organization; LMN=letter of medical necessity; LOA=letter of appeal; OOP=out-of-pocket; PA=prior authorization.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

Product overview

Description[1]	• Supplied as a sterile, preservative-free, white lyophilized powder in a single-dose vial • Each single-dose vial (NDC 68727-950-01) contains 300 mg zanidatamab-hrii • Each carton of ZIIHERA (NDC 68727-950-02) contains 2 single-dose vials
Average number of vials per patient[1,2]	89 vials *The average number of patient vials is calculated based on weights of <70 kg and ≥70 kg and a median duration of treatment of 43.1 weeks for patients who received ZIIHERA + CT + tislelizumab and 31 weeks for patients who received ZIIHERA + CT in HERIZON-GEA-01.*
Storage[1]	Store in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF) in the original carton until time of reconstitution. Do not freeze.
Recommended dosing[1]	The regimen is based on weight and dosing amount until disease progression or unacceptable toxicity: • For patients weighing <70 kg: 1,800 mg every 3 weeks or 1,200 mg every 2 weeks • For patients weighing ≥70 kg: 2,400 mg every 3 weeks or 1,600 mg every 2 weeks
Dosing regimen[1]	For the recommended dosage of CT or tislelizumab to be administered in combination with ZIIHERA, refer to the respective Prescribing Information. When ZIIHERA is administered in combination with fluorouracil-containing regimens, administer fluorouracil as an IV infusion. Do NOT administer fluorouracil as an IV bolus due to the potential increase in diarrhea. If CT is discontinued for reasons other than disease progression, treatment with ZIIHERA, and/or tislelizumab can continue until disease progression.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[3,4,a]

National Comprehensive Cancer Network® (NCCN®) recommends HER2 testing for patients with gastric cancer at the time of diagnosis if advanced/metastatic disease is documented or suspected. NCCN recommends HER2 testing for patients with esophageal or EGJ adenocarcinoma at the time of diagnosis if metastatic adenocarcinoma is documented or suspected.[b]

[a]NCCN makes no warranties of any kind regarding their content, use or application and disclaims any responsibility for their application or use in any way. Category 2A recommendations are based upon lower-level evidence and there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.[3,4]

[b]IHC/ISH/targeted PCR testing methods are preferred initially; NGS through a CLIA-approved laboratory may be considered later in the clinical course with sufficient tumor tissue available for testing.[3,4]

CLIA=Clinical Laboratory Improvement Amendments; EGJ=esophagogastric junction; HER2=human epidermal growth factor receptor 2; IHC=immunohistochemistry; ISH=*in situ* hybridization; IV=intravenous; NCCN=National Comprehensive Cancer Network® (NCCN®); NDC=National Drug Code; NGS=next-generation sequencing; PCR=polymerase chain reaction.

Key considerations for reimbursement

ZIIHERA billing and coding requirements will vary based on many factors, including the site of service where the drug is administered, the type of insurance the patient has, and the benefit under which ZIIHERA is covered.

Benefit category

Most payers cover physician-administered products such as ZIIHERA under a medical benefit rather than a pharmacy benefit. For Medicare, while ZIIHERA will typically be covered under Part B, private payers and Medicaid, including managed Medicaid, may require that physicians obtain ZIIHERA through a specialty pharmacy. Specialty pharmacies may bill the payer under the medical or pharmacy benefit, depending on what that payer requires.

Coverage guidance for physician offices and hospital outpatient facilities

For patients enrolled in Medicaid, a Medicare Advantage plan, or a commercial health plan, coverage of ZIIHERA will vary by payer and may also be subject to utilization restrictions.

For Medicare patients, ZIIHERA will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary. There are no precertification requirements for ZIIHERA under traditional fee-for-service.

Site of service

ZIIHERA may be administered in physicians' offices or in hospital outpatient departments. For most payers, the site of service will affect the billing and coding requirements. This guide focuses on coverage, coding, and billing for ZIIHERA when administered in physicians' offices and hospital outpatient settings.

INSURANCE AND COVERAGE SUPPORT

Navigating insurance requirements is a critical step in ensuring timely access to ZIIHERA for your patients. This section provides practical tools and guidance to help office staff manage the coverage process efficiently once you prescribe ZIIHERA.

JazzCares works directly with healthcare providers and office staff to help verify insurance coverage for eligible patients and offer support throughout the insurance coverage process. More information about JazzCares can be found on page 16.

PA and benefits verification

Payers may require PA, meaning prescribers will need to provide additional patient information, documentation of first-line treatment with another medication, or other clinical data for ZIIHERA to qualify for coverage.

When calling a payer to verify benefits and inquire about PA, the following key questions should be considered.

Verify patient eligibility and benefits with the payer before providing ZIIHERA.

☑ **What is the patient's copayment, coinsurance, deductible, or out-of-pocket maximum?**

- Has it been met? If not, what amount has been applied to date?

☑ **Does the patient have an annual or lifetime benefit maximum?**

- Has it been met? If not, what amount has been applied to date?

☑ **Does the patient have other insurance benefits that will need to be coordinated?**

☑ **Is PA required? If so, what are the submission requirements for ZIIHERA?**

- J-code to report ZIIHERA
- Number of units
- Where and how to submit PA
- PA process
- Required documentation (eg, forms, prescribing information, and statement of medical necessity)
- Is there a medical policy in place for GEA and/or ZIIHERA?
- How long will it take?

☑ **Check criteria for reauthorization and obtain appropriate documentation**

Letter of medical necessity

A health plan may request a letter of medical necessity to support coverage of ZIIHERA. The letter helps explain the physician's rationale and clinical decision-making in choosing therapy for a specific patient and may include supporting documentation (see examples below). The letter may be submitted as part of the PA process, with the claim form, as part of an appeal, or in response to a health plan's request for additional documentation.

The checklist below and sample letter of medical necessity on the next page provide a guide to the type of information that is usually required when drafting the letter. This will help ensure your communications with health plans regarding medical necessity are as complete as possible.

Below is a checklist of items that may be needed to support the development of your letter of medical necessity.

Patient information:

- ☑ **Patient name**
- ☑ **Patient date of birth**
- ☑ **Insurance ID**
- ☑ **Insurance group number**
- ☑ **Case ID (if applicable)**

Clinical rationale:

- ☑ **Patient diagnosis**
- ☑ **Rationale for selecting ZIIHERA**
- ☑ **Test results and chart notes**
- ☑ **Hospital admission and/or emergency room notes**

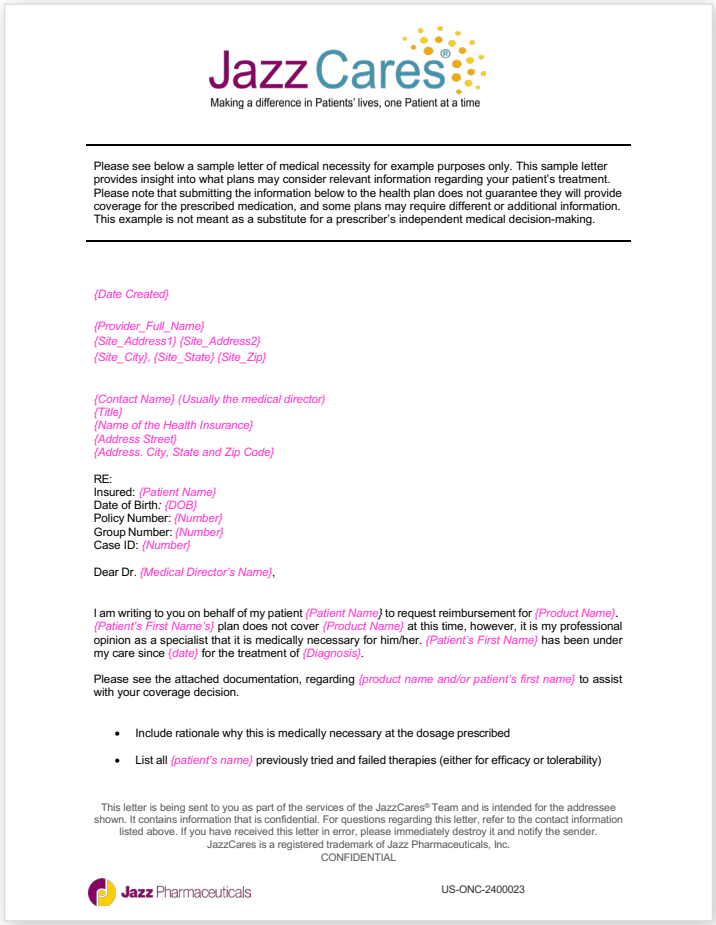
Additional supporting documentation may vary between health plans, but may include:

- ☑ **Prescribing information**
- ☑ **Documentation required by PA, if any**
- ☑ **Relevant peer-reviewed articles**

Sample letter of medical necessity

The sample letter provides insight into what health plans may consider relevant information regarding your patient's treatment. Download the template here to incorporate it into your letterhead.

Please note that submitting the letter to the health plan does not guarantee coverage for the prescribed medication, and some plans may require different or additional information. This example is not meant as a substitute for a prescriber's independent medical decision-making.



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Please see below a sample letter of medical necessity for example purposes only. This sample letter provides insight into what plans may consider relevant information regarding your patient's treatment. Please note that submitting the information below to the health plan does not guarantee they will provide coverage for the prescribed medication, and some plans may require different or additional information. This example is not meant as a substitute for a prescriber's independent medical decision-making.

{Date Created}

{Provider_Full_Name}
{Site_Address1} {Site_Address2}
{Site_City}, {Site_State} {Site_Zip}

{Contact Name} (Usually the medical director)
{Title}
{Name of the Health Insurance}
{Address Street}
{Address. City, State and Zip Code}

RE:
Insured: *{Patient Name}*
Date of Birth*: {DOB}*
Policy Number: *{Number}*
Group Number: *{Number}*
Case ID: *{Number}*

Dear Dr. *{Medical Director's Name}*,

I am writing to you on behalf of my patient *{Patient Name}* to request reimbursement for *{Product Name}*. *{Patient's First Name's}* plan does not cover *{Product Name}* at this time, however, it is my professional opinion as a specialist that it is medically necessary for him/her. *{Patient's First Name}* has been under my care since *{date}* for the treatment of *{Diagnosis}*.

Please see the attached documentation, regarding *{product name and/or patient's first name}* to assist with your coverage decision.

- Include rationale why this is medically necessary at the dosage prescribed
- List all *{patient's name}* previously tried and failed therapies (either for efficacy or tolerability)

This letter is being sent to you as part of the services of the JazzCares® Team and is intended for the addressee shown. It contains information that is confidential. For questions regarding this letter, refer to the contact information listed above. If you have received this letter in error, please immediately destroy it and notify the sender.
JazzCares is a registered trademark of Jazz Pharmaceuticals, Inc.
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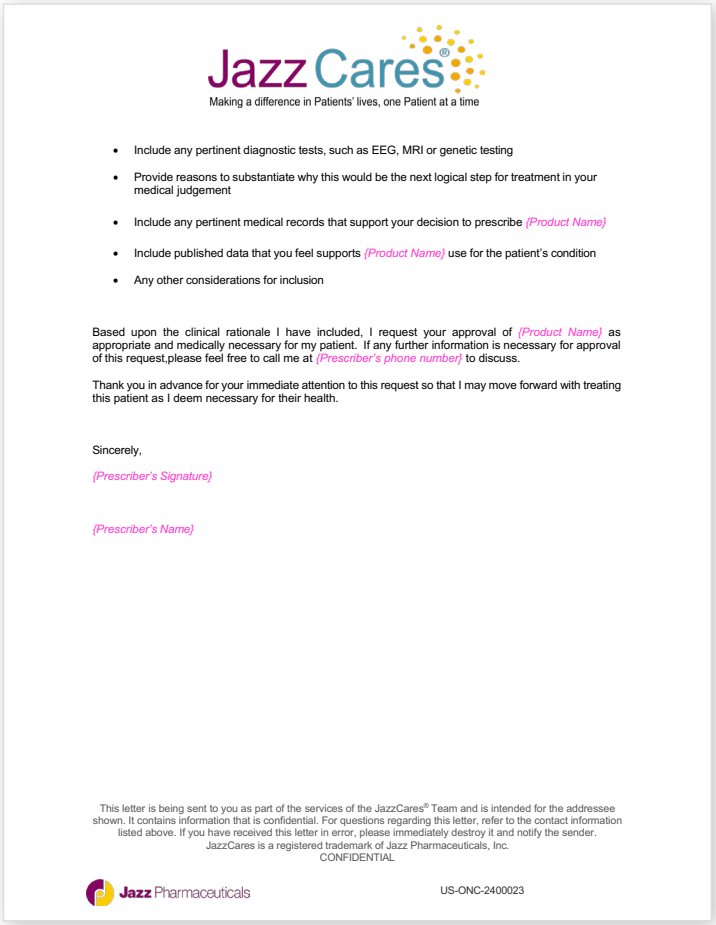

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- Include any pertinent diagnostic tests, such as EEG, MRI or genetic testing
- Provide reasons to substantiate why this would be the next logical step for treatment in your medical judgement
- Include any pertinent medical records that support your decision to prescribe *{Product Name}*
- Include published data that you feel supports *{Product Name}* use for the patient's condition
- Any other considerations for inclusion

Based upon the clinical rationale I have included, I request your approval of *{Product Name}* as appropriate and medically necessary for my patient. If any further information is necessary for approval of this request,please feel free to call me at *{Prescriber's phone number}* to discuss.

Thank you in advance for your immediate attention to this request so that I may move forward with treating this patient as I deem necessary for their health.

Sincerely,

{Prescriber's Signature}

{Prescriber's Name}

This letter is being sent to you as part of the services of the JazzCares® Team and is intended for the addressee shown. It contains information that is confidential. For questions regarding this letter, refer to the contact information listed above. If you have received this letter in error, please immediately destroy it and notify the sender.
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Letter of appeal

When a patient's health plan denies a PA request for ZIIHERA, you can submit a letter of appeal in response to the official denial letter. In the letter of appeal, you can explain your clinical rationale for prescribing ZIIHERA, provide supporting documentation that addresses the reason(s) given for the denial, and request approval.

The checklist below and sample letter on the next page provide a guide to the type of information that is usually required when drafting the letter. This will help ensure your communications with health plans regarding an appeal are as complete as possible. Incorrect or incomplete submissions may delay the review process or result in an automatic denial of the request.

Below is a checklist of items that may be needed to support the development of your letter of appeal.

Patient information:

- ☑ **Patient name**
- ☑ **Patient date of birth**
- ☑ **Insurance ID**
- ☑ **Insurance group number**
- ☑ **Case ID (if applicable)**

Clinical rationale:

- ☑ **Patient diagnosis**
- ☑ **Rationale for selecting ZIIHERA**
- ☑ **Test results and chart notes**
- ☑ **Hospital admission and/or emergency room notes**

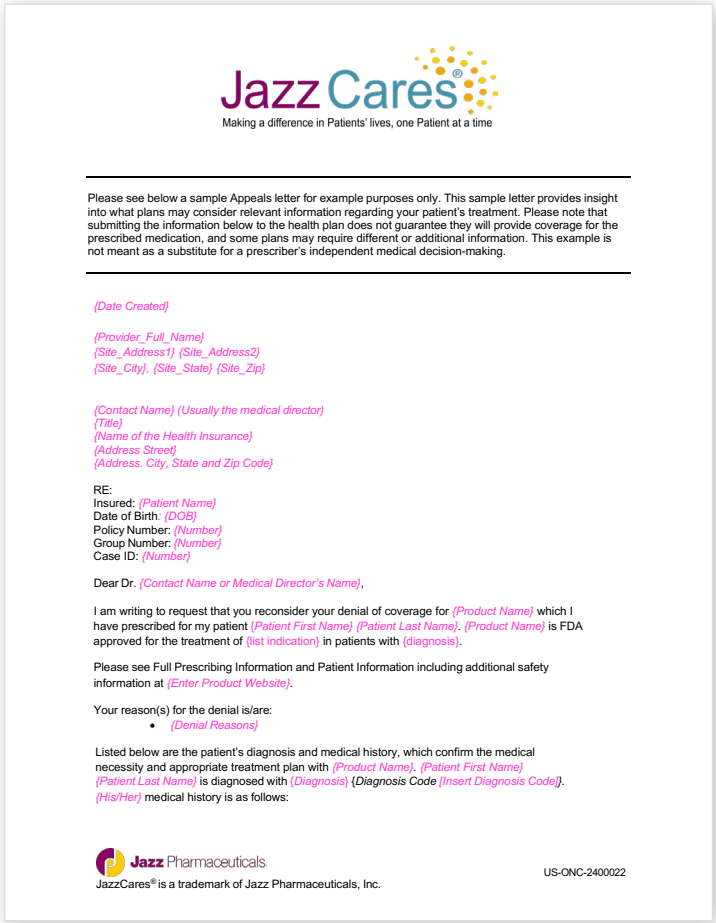
Additional supporting documentation may vary between health plans, but may include:

- ☑ **Prescribing information**
- ☑ **Relevant peer-reviewed articles**
- ☑ **For second- and third-level appeals, include a copy of the previous denial letter(s)**

Sample letter of appeal

The sample letter provides insight into what health plans may consider relevant information regarding your patient's treatment. Download the template here to incorporate it into your letterhead.

Please note that submitting the letter to the health plan does not guarantee coverage for the prescribed medication, and some plans may require different or additional information. This example is not meant as a substitute for a prescriber's independent medical decision-making.



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Please see below a sample Appeals letter for example purposes only. This sample letter provides insight into what plans may consider relevant information regarding your patient's treatment. Please note that submitting the information below to the health plan does not guarantee they will provide coverage for the prescribed medication, and some plans may require different or additional information. This example is not meant as a substitute for a prescriber's independent medical decision-making.

{Date Created}

{Provider_Full_Name}
{Site_Address1} {Site_Address2}
{Site_City}, {Site_State} {Site_Zip}

{Contact Name} (Usually the medical director)
{Title}
{Name of the Health Insurance}
{Address Street}
{Address. City, State and Zip Code}

RE:
Insured: *{Patient Name}*
Date of Birth: *{DOB}*
Policy Number: *{Number}*
Group Number: *{Number}*
Case ID: *{Number}*

Dear Dr. *{Contact Name or Medical Director's Name}*,

I am writing to request that you reconsider your denial of coverage for *{Product Name}* which I have prescribed for my patient *{Patient First Name} {Patient Last Name}*. *{Product Name}* is FDA approved for the treatment of {list indication} in patients with {diagnosis}.

Please see Full Prescribing Information and Patient Information including additional safety information at *{Enter Product Website}*.

Your reason(s) for the denial is/are:

- *{Denial Reasons}*

Listed below are the patient's diagnosis and medical history, which confirm the medical necessity and appropriate treatment plan with *{Product Name}*. *{Patient First Name} {Patient Last Name}* is diagnosed with *{Diagnosis}* {*Diagnosis Code [Insert Diagnosis Code]*}. *{His/Her}* medical history is as follows:

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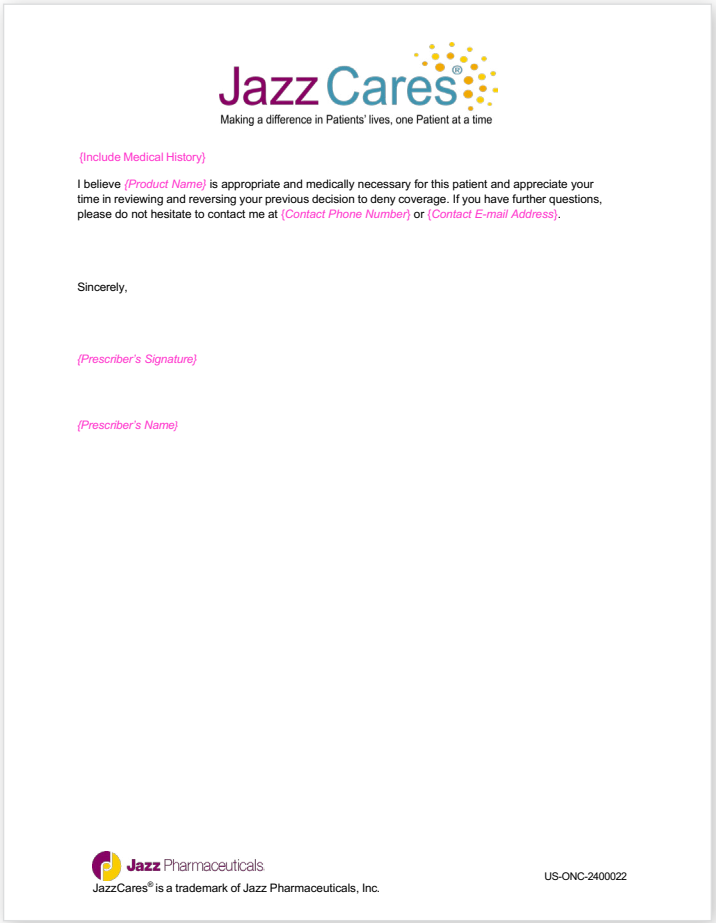

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{Include Medical History}

I believe *{Product Name}* is appropriate and medically necessary for this patient and appreciate your time in reviewing and reversing your previous decision to deny coverage. If you have further questions, please do not hesitate to contact me at *{Contact Phone Number}* or {*Contact E-mail Address*}.

Sincerely,

{Prescriber's Signature}

{Prescriber's Name}

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Claims filing checklist

The following tips may assist you with successfully filing claims for an infusion therapy. See the next 2 pages for sample claim forms.

☑ **Use appropriate codes to report the patient's condition, the drugs the patient received, and the services you have provided**

- J-code
- CPT code
- ICD-10-CM code
- Document waste if necessary per payer protocol

See additional coding information starting on page 13.

☑ **Include additional information requested by the payer in box 19 of the CMS-1500 form or in box 80 of the CMS-1450**

- ZIIHERA
- Dosage
- NDC
- Route of administration
- Unit description

☑ **Attach additional information to the claim if necessary**

- Letter of medical necessity
- Prescribing information
- Patient notes

☑ **Review claim for accuracy, including patient identification numbers, coding, and number of units**

☑ **File claim as soon as possible and within payer filing time limits**

☑ **Reconcile claim reports promptly and thoroughly to ensure claims have been appropriately processed and paid**

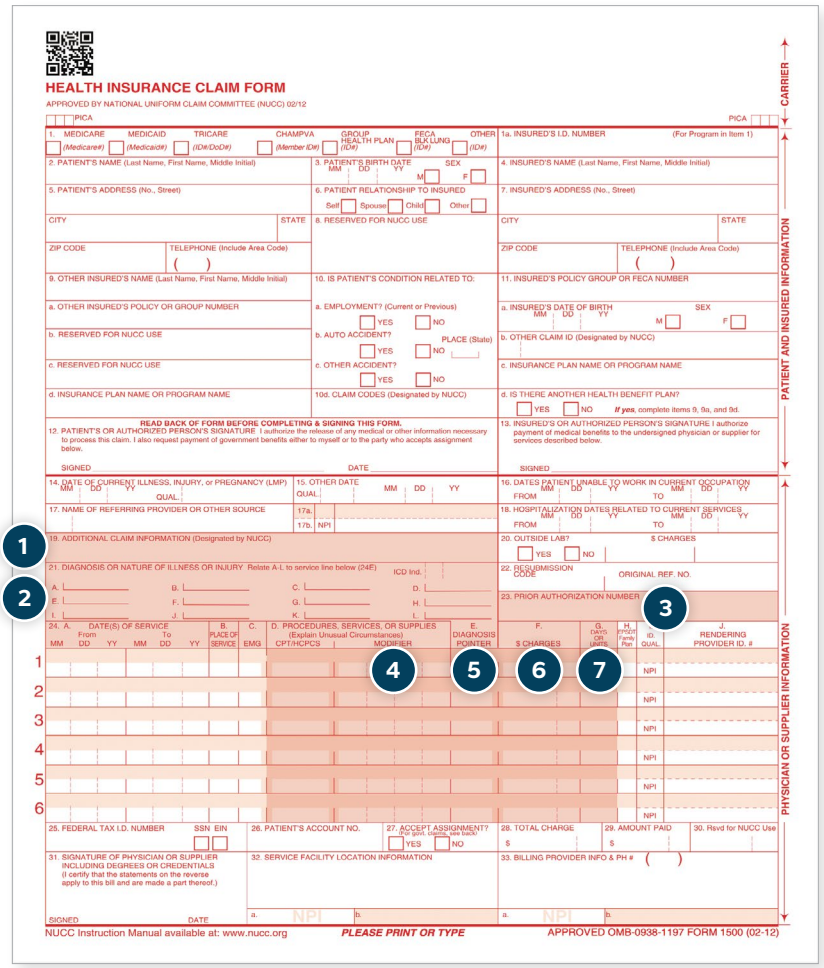
☑ **Verify that payment amounts correspond with your public payer allowables and your private payer contract**

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, Tenth Edition, Clinical Modification.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

CMS-1500 claim form for physician office administration

This sample claim form is provided only as an example. The healthcare provider is responsible for determining appropriate codes for an individual patient for related and/or separate procedures and for completing the appropriate forms.



1 Field 19

This area may be used to list the drug name, NDC,[a,b] dosage, strength, and route of administration.

2 Field 21

Enter the appropriate ICD-10-CM diagnosis code corresponding to the patient's diagnosis.

3 Field 23

If required, report the PA number here.

4 Field 24D

Enter the CPT code representing procedures performed and enter the permanent J-code with appropriate modifiers[b,c]:

For a nondiscarded claim, use 1 line: Enter the permanent J-code to report the use of ZIIHERA and enter modifier JZ to indicate no waste. Repeat as needed to report the use of any additional drug(s).

For a waste-required claim, use 2 lines: On 1 line, enter the permanent J-code to report the use of ZIIHERA and do not enter a modifier. On a separate line, enter the permanent J-code to report the waste of ZIIHERA and enter modifier JW to indicate waste. Repeat as needed to report the use and waste of any additional drug(s).

5 Field 24E

Specify diagnosis from Field 21 relating to each CPT/J-code listed in Field 24D.

6 Field 24F

Enter the charge for each listed service and calculate the submitted price for the amount of drug administered. If modifier JW is required in Field 24D, calculate the submitted price for the amount of drug wasted on the corresponding line.[b]

7 Field 24G

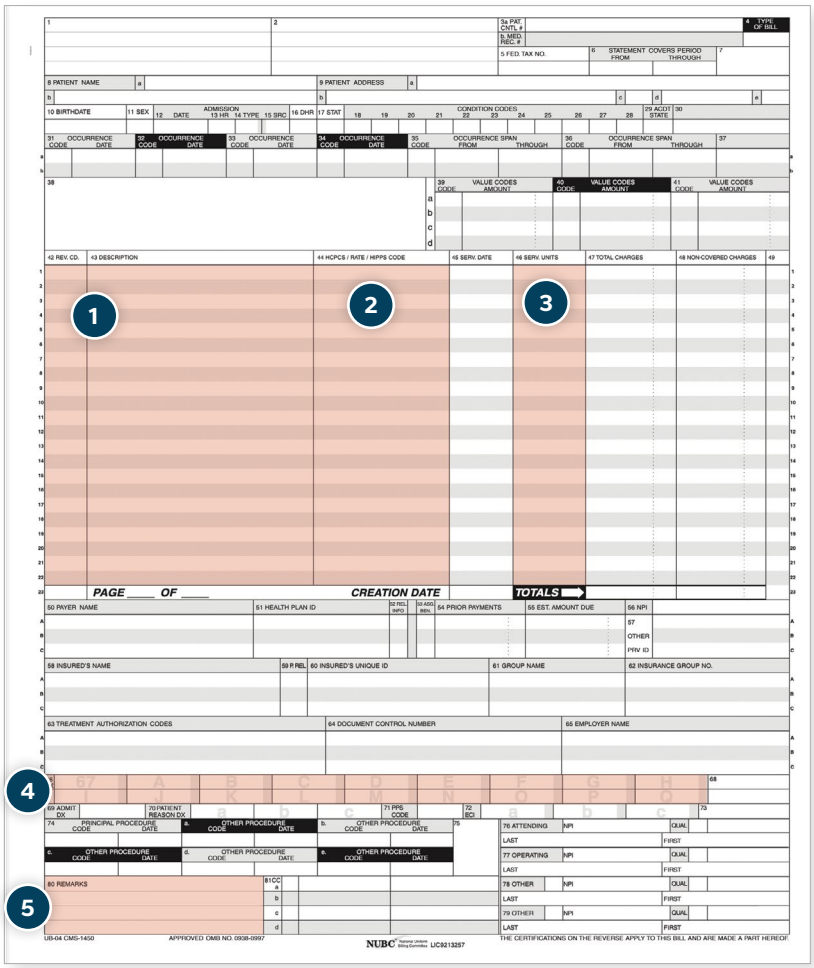
Enter the number of units administered. If modifier JW is required in Field 24D, enter the number of units wasted on the corresponding line.[b]

[a]Please note that for billing purposes, the NDC requires 11 digits (thus a zero has been entered into the sixth digit). This is consistent with the Red Book and First Databank listings.
[b]Contact your Medicare contractor and/or all other contracted/noncontracted payer(s) for any questions regarding filling guidelines for coverage, coding, and payment.
[c]Providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records. Note, either the JW or JZ modifier must be reported, but claims should not include both.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

UB-04 (CMS-1450) claim form for hospital outpatient administration

This sample claim form is provided only as an example. The healthcare provider is responsible for determining appropriate codes for an individual patient for related and/or separate procedures and for completing the appropriate forms.



1 Fields 42 and 43

Enter the appropriate revenue code (Field 42) and corresponding description (Field 43).

2 Field 44

Enter the CPT code representing procedures performed and enter the permanent J-code with appropriate modifiers[a,b]:

For a nondiscarded claim, use 1 line: Enter the permanent J-code to report the use of ZIIHERA and enter modifier JZ to indicate no waste. Repeat as needed to report the use and waste of any additional drug(s).

For a waste-required claim, use 2 lines: On 1 line, enter the permanent J-code to report the use of ZIIHERA and do not enter a modifier. On a separate line, enter the permanent J-code to report the waste of ZIIHERA and enter modifier JW to indicate waste. Repeat as needed to report the use and waste of any additional drug(s).

3 Field 46

Enter the number of units administered. If modifier JW is required in Field 44, enter the number of units wasted on the corresponding line.[a]

4 Field 66

Enter the diagnosis code.

5 Field 80

Product information: Billing with a specific J-code allows for faster payment through electronic billing. Manual billing may still be required in certain circumstances.

In those cases, it may be necessary to provide the following product information for payment: NDC, quantity of the drugs administered (expressed in unit of measure applicable to the drug or biological), and the date the drug was administered to the patient.

[a]Contact your Medicare contractor and/or all other contracted/noncontracted payer(s) for any questions regarding filling guidelines for coverage, coding, and payment.
[b]Providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records. Note, either the JW or JZ modifier must be reported, but claims should not include both.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

BILLING, CODING, AND ORDERING

This section provides sample codes for hospitals and physician offices for GEA. Note that many of the codes are the same whether the site of care is inpatient or outpatient.

ICD-10-CM codes[5]

ICD-10-CM codes for esophageal and GEJ

Code	Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia (includes gastro-esophageal junction, cardiac orifice, cardio-esophageal junction)
C16.9	Malignant neoplasm of stomach, unspecified

ICD-10-CM codes for gastric cancer

Code	Description
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified

HCPCS code

Permanent J-code[6]	Description[6]	HCPCS code dosage (billing units)[6]	Example
J9276	Injection, zanidatamab-hrii, 2 mg	2 mg = 1 unit	300 mg vial[1] = 150 units

ICD-10-PCS codes[7]

Code	Description
XW033CA	Introduction of zanidatamab antineoplastic into peripheral vein, percutaneous approach, new technology group 10
XW043CA	Introduction of zanidatamab antineoplastic into central vein, percutaneous approach, new technology group 10

CPT codes[8]

Code	Description
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique, each additional hour

The sample codes on pages 13-14 are based on publicly available information, are informational only, and are not a guarantee or promise of coverage. Appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements.

GEJ=gastroesophageal junction; HCPCS=Healthcare Common Procedure Coding System; ICD-10-PCS=International Classification of Diseases, Tenth Revision, Procedure Coding System.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

BILLING, CODING, AND ORDERING (CONT.)

HCPCS modifier codes[9]

Code	Description
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities

Note: Starting January 1, 2025, CMS is requiring all 340B covered entities to report the TB modifier on claims.[10]

Place of service codes[11]

Code	Location	Description
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
19	Off campus-outpatient hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
22	On campus-outpatient hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

Revenue codes[12]

Code	Description
0250	Pharmacy - general
0260	IV therapy - general
0510	Clinic - general
0636	Pharmacy - drugs requiring detailed coding

NDC codes[1]

10-digit code	11-digit code	Description
68727-950-01	68727-0950-01	Single-dose vial of ZIIHERA
68727-950-02	68727-0950-02	Carton containing 2 single-dose vials of ZIIHERA

The sample codes on pages 13-14 are based on publicly available information, are informational only, and are not a guarantee or promise of coverage. Appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements.

Note: Payers may require a 10-digit or 11-digit NDC. Both are provided for your convenience.

CY=calendar year.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

Specialty distribution

ZIIHERA is available for purchase from the authorized specialty distributors and group purchasing organizations (GPOs) listed below. Verify that your facility has an account with the specialty distributor before ordering. If not, they should contact the specialty distributor. The facility should also contact the specialty distributor with questions regarding product returns, specific pricing, and payment terms.

BioCare

BioCareSD®	Specialized Oncology Support
Web: https://store.biocaresd.com/biocare/en/USD/login **Phone:** 1-800-304-3064 **Email:** order@biocaresd.com	**Web:** https://biocare-us.com/our-companies/biocaresd/ **Phone:** 1-855-202-6699 **Email:** customercare@biocaresd.com

cencora

ASD Healthcare	Oncology Supply
Web: https://www.asdhealthcare.com **Phone:** 1-800-746-6273 **Fax:** 1-800-547-9413 **Email:** service@asdhealthcare.com	**Web:** www.oncologysupply.com **Phone:** 1-800-633-7555 **Fax:** 1-800-248-8205 **Email:** service@oncologysupply.com

CardinalHealth™

For oncology clinics	For hospitals
Web: specialtyonline.cardinalhealth.com **Phone:** 1-877-453-3972 **Fax:** 1-877-274-9897 **Email:** SPDOncologyTeam@cardinalhealth.com	**Web:** orderexpress.cardinalhealth.com **Phone:** 1-855-855-0708 **Fax:** 1-877-274-9897 **Email:** SPDOncologyTeam@cardinalhealth.com

MCKESSON

McKesson Plasma & Biologics	McKesson Specialty Health Distribution
Web: https://connect.mckesson.com **Phone:** 1-877-625-2566 **Fax:** 1-888-725-7626 **Email:** MPBOrders@mckesson.com	**Web:** https://mscs.mckesson.com **Phone:** 1-800-482-6700 **Fax:** 1-800-289-9285 **Email:** MSH-CustomerCare@mckesson.com

Community practice GPO partners

ION Solutions (Cencora) | Onmark® GPO (McKesson) | Unity Group (The US Oncology Network/McKesson) | VitalSource™ (Cardinal Health™)

JazzCares helps eligible patients get access to ZIIHERA

JazzCares is sponsored by Jazz Pharmaceuticals to help improve access to Jazz medications for appropriate patients (eligibility requirements may apply).

JazzCares®
Making a difference in Patients' lives, one Patient at a time

JazzCares supports patients

Assists with benefits investigations,[a] PAs and appeals, and referrals to other financial assistance options for eligible patients

Patient Assistance Program for eligible patients

Uninsured or underinsured patients who are eligible may receive ZIIHERA at no cost

Reduction of out-of-pocket costs for eligible patients

Savings Card—eligible, commercially insured patients can pay as little as $0

Enroll your patient in JazzCares

1. Patients complete, sign, and submit the online **JazzCares Consent Form**

Download JazzCares Consent Form →

2. Complete, sign, and submit the online **JazzCares Enrollment Form**

Download JazzCares Enrollment Form →

Forms can also be faxed or mailed to JazzCares by downloading and completing the forms from the links above:

- Fax to 1-855-593-3955 OR
- Mail to JazzCares Program, PO Box 5490, Louisville, KY 40255

Field Access Navigators (FANs) provide expertise and support to healthcare providers

- Assistance with reimbursement-related questions and JazzCares patient support services
- Purchasing, procurement, and distribution support
- Education on coding, billing, and JazzCares financial assistance programs

For more information about JazzCares, click here, call 1-833-533-JAZZ (5299), Monday-Friday, 8 AM-8 PM ET, or contact your FAN

Insurance coverage and plans may vary. The JazzCares Program at Jazz Pharmaceuticals provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

ZIIHERA® (zanidatamab-hrii)
50mg/ml Injection for IV

FREQUENTLY ASKED QUESTIONS

Access and reimbursement

ZIIHERA is not listed on my formulary, can I still access the product?

There is typically a path to access a drug prior to formulary inclusion. If you have any access related questions, please refer to your FAN/PVO team.

How does the reimbursement process differ when ZIIHERA is billed under the pharmacy benefit?

ZIIHERA is administered as an IV infusion and billed under the medical benefit. However, if a plan allows it to be billed under the pharmacy benefit, the reimbursement workflow changes:

- **Prior authorization:** ZIIHERA will require a pharmacy PA, which is handled directly by the PBM. Providers must submit required clinical documentation to the PBM
- **Drug acquisition:** The PBM usually requires that ZIIHERA be dispensed by a contracted specialty pharmacy and shipped to the practice or directly to the patient
- **Claim billing:** Providers should bill for administration only
- **Financial assistance:** JazzCares operates across both benefit types. Eligible, commercially insured patients can pay as little as $0 for their medication, subject to an annual maximum (restrictions apply)

Contact your FAN with any specific questions about navigating the reimbursement process.

How should I handle any applicable step therapy requirements?

Step therapy requirements will differ depending on a given health plan or payer.

What documentation is typically required by payers for HER2 status confirmation?

Typically, a pathology report including testing methodology (IHC, IHS, targeted PCR, or in some cases NGS) and results will be needed.

Ordering and distribution

How do I order ZIIHERA?

ZIIHERA will be available through the following 4 distributors: BioCare, ASD/Oncology Supply, McKesson/Plasma Biologic/McKesson Specialty Health, or Cardinal Specialty Distribution. If you need access through a specialty pharmacy, please contact your FAN.

See page 15 for more details about specialty distribution.

Can I purchase ZIIHERA through my GPO?

Yes. Our GPO partners include: ION Solutions (Cencora), Onmark GPO (McKesson), Unity Group (The US Oncology Network/McKesson) and VitalSource (Cardinal Health).

PBM=pharmacy benefit manager; PVO=Payer Value and Outcomes.

Ordering and distribution (cont.)

How soon can I get ZIIHERA?

Our team can guarantee availability of ZIIHERA within the next business day upon commercial availability.

How many vials are in a pack?

ZIIHERA is supplied in a carton containing 2 single-dose vials. The carton has an NDC of 68727-950-02 and each single-dose vial within the carton has an NDC of 68727-950-01.[1]

Are you offering extended payment terms?

Please contact your specialty distributor regarding extended payment terms: BioCare, ASD/Oncology Supply, McKesson/Plasma Biologic/McKesson Specialty Health, or Cardinal Specialty Distribution.

See page 15 for more details about specialty distribution

Pricing and cost

How much does ZIIHERA cost vs other HER2-targeted therapies for GEA?

I can refer you to your FAN to discuss cost-related questions. Alternatively, you can contact your community practice GPO partner: ION Solutions (Cencora), Onmark GPO (McKesson), Unity Group (The US Oncology Network/McKesson), or VitalSource (Cardinal Health).

If you have additional questions, click here to contact your Jazz FAN or see contact information on page 1

Your Jazz team

Field Access Navigator (FAN)

Collaborates with you, your office, and outpatient provider care centers to offer insights on payer and reimbursement policies, expertise on Jazz's patient support services, information on product procurement, billing and coding, and the availability of financial assistance programs for your patients.

Name: _____ **Phone number:** _____

Email: _____

Oncology Business Manager (OBM)

Serves as a central point of contact for you and your practice. OBMs coordinate with cross-functional teams to deliver solutions that include identifying and helping navigate payer, financial, administrative, and operational barriers, as well as supporting timely and appropriate patient access to therapy. OBMs also have a deep understanding of GPOs, contracting, and health economics.

Name: _____ **Phone number:** _____

Email: _____

Oncology Account Manager (OAM)

Helps address clinical needs for you and your patients. OAMs convey their expertise and knowledge of Jazz's oncology therapeutic area to you and your patient care team through live interaction or virtual platforms, which may provide you with a better understanding of our products.

Name: _____ **Phone number:** _____

Email: _____

Medical Science Liaison

Provides academic and scientific expertise pertaining to any of Jazz's oncology products and related disease states. If you have questions, contact the Medical Information Department at 1-800-520-5568 or via **medinfo-us@jazzpharma.com**.

Name: _____ **Phone number:** _____

Email: _____

Patient Support Services

JazzCares is committed to helping your patients get access to their medication by providing personalized support throughout their treatment journey. For more information, visit **www.jazzcares.com** or call **1-833-533-JAZZ (5299)**.

Adverse event reporting

In the United States, **email AEReporting@JazzPharma.com** to report an adverse event or product complaint for ZIIHERA.

Compliance reporting

Jazz is committed to conducting our business with integrity and pursuing excellence in all that we do. Jazz has established various methods of confidential communication for our employees, vendors, and others to report suspected violations of laws, rules, regulations, or company policies. Where permitted by local laws, anonymous reporting is available by calling **1-800-511-2034** or visiting **https://jazzpharma.caseiq.app/portal**.

Please see additional Important Safety Information on pages 21-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

ZIIHERA® (zanidatamab-hrii) 50mg/ml Injection for IV

ADDITIONAL RESOURCES (CONT.)

Product information

Dosing and Administration Guide

Download

Product Flashcard

Download

Patient access and support

JazzCares Enrollment Form

Download

e-Enroll

JazzCares Patient Consent Form

Download

e-Enroll

JazzCares Patient Support Flashcard

Download

Sample Letter of Medical Necessity

Download

Sample Letter of Appeal

Download

IMPORTANT SAFETY INFORMATION

WARNING: DIARRHEA and EMBRYO-FETAL TOXICITY

- **ZIIHERA, in combination with fluoropyrimidine- and platinum-containing chemotherapy, with or without tislelizumab-jsgr, can cause severe diarrhea, including life threatening and fatal cases. Use antidiarrheal prophylaxis during the first cycle when ZIIHERA is given in combination with these drugs. Manage with antidiarrheals and supportive measures as clinically indicated. Interrupt, reduce the dose or discontinue ZIIHERA based on severity.**
- **Embryo-Fetal Toxicity: Exposure to ZIIHERA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.**

Diarrhea
ZIIHERA can cause severe diarrhea.

When ZIIHERA is used in combination with fluoropyrimidine- and platinum-containing chemotherapy with or without tislelizumab-jsgr, severe, life threatening, and fatal cases of diarrhea can occur despite loperamide prophylaxis. The risk of severe and life threatening diarrhea is higher when ZIIHERA is administered with chemotherapy and tislelizumab-jsgr, with a higher risk in patients aged ≥ 65 years compared to younger patients. Advise patients to increase oral fluids, begin antidiarrheals, and notify their healthcare provider immediately if diarrhea occurs.

Administer antidiarrheal prophylaxis with loperamide in cycle 1 for all patients receiving ZIIHERA in combination with fluoropyrimidine- and platinum-containing chemotherapy with or without tislelizumab-jsgr. Begin loperamide at the first loose stool when ZIIHERA is administered in combination with chemotherapy. Administer fluids, electrolytes, and additional antidiarrheal agents as necessary. Before modifying the dose of ZIIHERA, evaluate, modify or discontinue drug(s) contributing to diarrhea in accordance with their respective prescribing information. Withhold, reduce the dose, or permanently discontinue ZIIHERA based on severity.

If treating patients with ZIIHERA in combination with FOLFOX, do not administer the fluorouracil bolus.

ZIIHERA in combination with chemotherapy and tislelizumab-jsgr

Diarrhea was reported in 85% of 330 patients in clinical studies, including Grade 4 (2.1%), Grade 3 (24%), and Grade 2 (31%) events. Fatal outcomes resulting from diarrhea occurred in 1.5% of patients. Diarrhea leading to dose reduction of ZIIHERA occurred in 10% of patients, and permanent discontinuation of ZIIHERA occurred in 3.9% of patients.

In cycle 1, diarrhea at Grade 4 severity occurred in 1.5% and Grade 3 severity occurred in 15% of patients despite use of loperamide prophylaxis. The median time to onset for cycle 1 diarrhea was 6 days and median time to resolution was 18 days.

ZIIHERA in combination with chemotherapy

Diarrhea was reported in 81% of 395 patients in clinical studies, including Grade 4 (1.3%), Grade 3 (20%) and Grade 2 (33%). Diarrhea leading to dose reduction of ZIIHERA occurred in 10% of patients, and permanent discontinuation of ZIIHERA occurred in 1.8% of patients.

In cycle 1, diarrhea at Grade 4 severity occurred in 0.8% and Grade 3 severity occurred in 14% of patients despite use of loperamide prophylaxis. The median time to onset for cycle 1 diarrhea was 6 days and median time to resolution was 18 days.

Embryo-Fetal Toxicity
Based on the mechanism of action, ZIIHERA can cause fetal harm when administered to a pregnant woman. There are no human or animal data on the use of ZIIHERA in pregnancy. In literature reports, use of a HER2-directed antibody during pregnancy resulted in cases of oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death.

Verify the pregnancy status of females of reproductive potential prior to the initiation of ZIIHERA. Advise pregnant women and females of reproductive potential that exposure to ZIIHERA during pregnancy or within 4 months prior to conception can result in fetal harm. Advise females of reproductive potential to use effective contraception while receiving ZIIHERA and for 4 months following the last dose of ZIIHERA.

Please see additional Important Safety Information on pages 22-23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

IMPORTANT SAFETY INFORMATION (CONT.)

Left Ventricular Dysfunction (LVD)
ZIIHERA can cause decreases in left ventricular ejection fraction (LVEF).

Assess LVEF prior to initiation of ZIIHERA and at regular intervals during treatment. Withhold dose or permanently discontinue ZIIHERA based on severity of adverse reactions.

The safety of ZIIHERA has not been established in patients with a baseline ejection fraction that is < 50%.

ZIIHERA in combination with chemotherapy and tislelizumab-jsgr

LVEF decrease (an absolute decline in LVEF of > 10%, resulting in a final value of < 50%) was observed in 9% of 330 patients in clinical studies. LVD leading to permanent discontinuation of ZIIHERA was reported in 3% of patients. Fatal outcomes due to LVD occurred in one patient (0.3%). The median time to first occurrence of LVD was 6.9 months (range: 1.2 to 29.1 months). LVD resolved in 78% of patients.

ZIIHERA in combination with chemotherapy

LVEF decrease was observed in 5% of 395 patients. LVD leading to permanent discontinuation of ZIIHERA was reported in 1.0% of patients. The median time to first occurrence of LVD was 6.0 months (range: 1.4 to 15.0 months). LVD resolved in 70% of patients.

Infusion-Related Reactions
ZIIHERA can cause infusion-related reactions (IRRs).

Prior to each dose of ZIIHERA, administer premedication to prevent potential IRRs. Monitor patients for signs and symptoms of IRR during ZIIHERA administration and as clinically indicated after completion of infusion. Have medications and emergency equipment to treat IRRs available for immediate use.

If an IRR occurs, slow or stop the infusion, and administer appropriate medical management. Monitor patients until complete resolution of signs and symptoms before resuming. Permanently discontinue ZIIHERA in patients with recurrent severe or life-threatening IRRs.

ZIIHERA in combination with chemotherapy and tislelizumab-jsgr

An IRR was reported in 22% of 330 patients in clinical studies, including Grade 4 (0.3%), Grade 3 (1.2%), and Grade 2 (16%) despite use of prophylaxis. IRRs leading to permanent discontinuation of ZIIHERA were reported in 0.3% of patients. IRRs occurred on the first day of dosing in 17% of patients. Of all patients who experienced IRRs, 60% of reactions resolved within the first day.

ZIIHERA in combination with chemotherapy

An IRR was reported in 24% of 395 patients in clinical studies, including Grade 4 (0.3%), Grade 3 (1.5%), and Grade 2 (18%) despite use of prophylaxis. IRRs leading to permanent discontinuation of ZIIHERA were reported in 1.3% of patients. IRRs occurred on the first day of dosing in 22% of patients. Of all patients who experienced IRRs, 83% of reactions resolved within the first day.

Adverse Reactions
ZIIHERA in combination with chemotherapy and tislelizumab-jsgr

Serious adverse reactions occurred in 59% of 294 patients in HERIZON-GEA-01. Serious adverse reactions in > 2% of patients included diarrhea (17%), IRR (5%), vomiting (4.8%), hypokalemia (4.4%), acute kidney injury (3.7%), pneumonia (3.7%), nausea (2.4%), decreased appetite (2.4%), and anemia (2.4%). Fatal adverse reactions occurred in 2.4% of patients and included acute kidney injury (N=2), cardiac failure, diarrhea, dehydration, hypovolemic shock and intestinal obstruction (all N=1).

Permanent discontinuation of ZIIHERA occurred in 13% of patients. Adverse reactions that resulted in permanent discontinuation of ZIIHERA in ≥ 1% of patients included diarrhea (4.4%) and ejection fraction decreased (2.7%).

The most common adverse reactions (≥ 20%) were diarrhea (83%), nausea (56%), decreased appetite (46%), vomiting (44%), hypokalemia (39%), fatigue (37%), rash (36%), peripheral neuropathy (27%), and IRR (25%).

Please see additional Important Safety Information on page 23 and full Prescribing Information, including BOXED WARNINGS and Medication Guide.

IMPORTANT SAFETY INFORMATION (CONT.)

Adverse Reactions (cont.)

ZIIHERA in combination with chemotherapy

Serious adverse reactions occurred in 49% of 305 patients in HERIZON-GEA-01. Serious adverse reactions in > 2% of patients included diarrhea (11%), vomiting (3.3%), decreased appetite (2.6%), pneumonia (2.6%), sepsis (2.6%), hypokalemia (2.3%), and nausea (2.3%).

Permanent discontinuation of ZIIHERA occurred in 10% of patients. Adverse reactions that resulted in permanent discontinuation of ZIIHERA in ≥ 1% of patients included ejection fraction decreased (2.0%), IRR (1.6%), and diarrhea (1.6%).

The most common adverse reactions (≥ 20%) were diarrhea (79%), nausea (54%), vomiting (44%), decreased appetite (40%), fatigue (36%), hypokalemia (33%), peripheral neuropathy (32%), IRR (25%), and rash (22%).

Pediatric Use

Safety and efficacy of ZIIHERA have not been established in pediatric patients.

Geriatric Use

ZIIHERA in combination with chemotherapy and tislelizumab-jsgr

Of 302 patients randomized to ZIIHERA in combination with chemotherapy and tislelizumab-jsgr in HERIZON-GEA-01, there were 139 (46%) patients aged ≥ 65 years. One hundred and six (35%) were aged 65-74 years and 33 (11%) were aged ≥ 75 years.

There was a higher incidence of Grade ≥ 3 adverse reactions observed in patients aged ≥ 65 years (87%) as compared to younger patients (80%). The incidence of Grade 3 or 4 diarrhea was higher in patients aged ≥ 65 years (32%) compared to younger patients (20%).

There was an increased incidence of fatal adverse reactions in patients aged ≥ 65 years (4.4%); including acute kidney injury (N=2), cardiac failure, dehydration, hypovolemic shock and intestinal obstruction (all N=1), compared to younger patients (0.6%), including diarrhea (N=1).

ZIIHERA in combination with chemotherapy

Of 304 patients randomized to ZIIHERA in combination with chemotherapy in HERIZON-GEA-01, there were 130 (43%) patients aged ≥ 65 years. One hundred (33%) were aged 65-74 years and 30 (10%) were aged ≥ 75 years.

No overall differences in safety were observed between patients aged ≥ 65 years and younger adult patients.

Please see full Prescribing Information, including BOXED WARNINGS and Medication Guide.

For more information about ZIIHERA, visit www.ZIIHERAhcp.com.

References: 1. ZIIHERA® (zanidatamab-hrii) Prescribing Information. Jazz Pharmaceuticals, Inc. **2.** Shitara K, Elimova E, Liu T, et al. Zanidatamab with and without tislelizumab in HER2-positive gastroesophageal cancer. *N Engl J Med*. 2026;394(20):2002- 2014. doi:10.1056/NEJMoa2517729. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer V.3.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed June 3, 2026. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. **4.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Esophageal and Esophagogastric Junction Cancers V.3.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed June 3, 2026. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. **5.** ICD-10-CM tabular list of diseases and injuries. Centers for Medicare & Medicaid Services website. https://www.cms.gov/files/zip/april-1-2026-code-tables-tabular-index.zip. Updated April 1, 2026. Accessed April 3, 2026. **6.** CMS website. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations. First quarter 2025 coding cycle for drug and biological products. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-1-2025-drugs-and-biologicals.pdf. Accessed May 7, 2026. **7.** ICD-10-PCS 2026 tables and index. Centers for Medicare & Medicaid Services website. https://www.cms.gov/medicare/coding-billing/icd-10-codes. Updated March 10, 2026. Accessed April 3, 2026. **8.** Coalition of Hematology and Oncology Practices. Welcome to coding guidelines presentation focusing on oncology billing. https://www.choptx.org/wp-content/uploads/2017/12/Coding-for-Oncology-Presentation-Final.v2pptx.pdf. Accessed August 22, 2026. **9.** Centers for Medicare & Medicaid Services. Billing 340B modifiers under the Hospital Outpatient Prospective Payment System (OPPS). https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf. Accessed August 22, 2026. **10.** Centers for Medicare & Medicaid Services. Medicare Part B inflation rebate guidance: use of the 340B modifier. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf. Accessed February 26, 2026. **11.** Centers for Medicare & Medicaid Services. Place of service code sets. https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets. Updated May 2, 2024. Accessed April 3, 2026. **12.** Noridian Healthcare Solutions. Revenue codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Updated February 12, 2026. Accessed February 24, 2026.

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Jazz Pharmaceuticals

ZIIHERA® (zanidatamab-hrii) 50mg/ml Injection for IV