ENHERTU Patient Assistance Programs Enrollment Form

ENHERTU® 4U
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

Application for patients prescribed ENHERTU to receive ENHERTU at no cost

Address: PO Box 221285
Charlotte, NC 28222

Phone: 1-833-ENHERTU

Fax: 1-833-904-1851

How to complete this application:

1. Review the information on this page carefully and work with your doctor to complete pages 2 and 3 of the application.
2. Have your doctor fax your completed, signed application to **1-833-904-1851**. You may NOT fax the application yourself. You or your doctor may also mail the application to:

   ENHERTU Patient Assistance Programs, PO Box 221285, Charlotte, NC 28222

Please do not send your medical records or Statement of Medical Necessity form with your application.

What are the ENHERTU Patient Assistance Programs?

- The ENHERTU Patient Assistance Programs (PAP) are offered by AstraZeneca/Daiichi Sankyo (AZ/DSI) to provide ENHERTU to qualifying patients at no cost. They are neither government programs nor insurance plans
- If you qualify, you may get free ENHERTU for up to 1 year, depending upon the Program in which you are enrolled. AZ/DSI will send you an application for renewal once your enrollment ends
- ENHERTU will be sent to your doctor's office due to specific handling requirements
- The Programs can be changed or stopped by AZ/DSI at any time or for any reason

Do you qualify for the Programs?

You may qualify for the Programs if:

✓ You have been prescribed ENHERTU by your physician.

✓ You must be a resident of the US.

✓ You must not have insurance, private or government, that covers ENHERTU (excluding Medicare).

✓ You must not be receiving any other assistance to help pay for ENHERTU.

✓ Your annual income must be at or below a certain level.

✓ **If you are a Medicare Beneficiary:**

- You must not be eligible for or enrolled in Extra Help/Low Income Subsidy for Medicare Part D
- You must have spent at least 3% of your annual household income on medicines in the current year

Please review your application to ensure it is complete and ready for submission.

Application for patients prescribed ENHERTU to receive ENHERTU at no cost (cont'd)

Important information about your application

Information provided to us will be used to determine possible eligibility for help from another program such as Medicaid. You may be required to submit documentation supporting that you do not qualify for other prescription assistance.

PATIENT INFORMATION: *For completion by Patient or Legally Authorized Representative*

☐ New Application ☐ Re-enrollment

Name: _____
First *Middle initial* *Last*

Address: _____

City: _____ State: _____ ZIP: _____ Date of Birth: _____ /_____ /_____
MM/DD/YYYY

☐ Patient has no current address.

Phone: (_____) _____ Mobile (_____) _____ Email: _____

Primary language spoken: ☐ English ☐ Spanish ☐ Other: _____

INSURANCE INFORMATION:

Coverage Type: ☐ Uninsured ☐ Medicare ☐ Commercial ☐ Other: _____

If you have coverage under Medicare, how much have you spent on medicines during the current year? $ _____

INCOME:

What is the total combined household income before taxes? (Include yourself, all adults, and all dependents)
Income Verification: The Program and its authorized third-party agents will use your date of birth or social security number and/or additional demographic information as needed to access your credit information and information derived from public and other sources to estimate your income in conjunction with the eligibility determination process. As a soft credit inquiry, this option will not impact your credit score.
The Program and its authorized third-party agents reserve the right to ask for additional documents and information at any time.

$ _____ Monthly OR $_____ Yearly

Number of people in your household: _____ Number of dependents in your household under 18 years of age: _____
(Include yourself, all adults, and all dependents)

Signature of Applicant or Parent/Legally Authorized Representative. If patient is a minor, parent or legally authorized representative should sign here.

Relation to Patient: ☐ Patient ☐ Parent/Legally Authorized Representative of Patient

Sign Here _____ **Date:** _____ /_____ /_____ **(MM/DD/YYYY)**

If someone helped you with this application and you want them to answer questions for you, please give us their name and phone number:

Helper's Name: _____ *Helper's Phone: (_____)* _____

**1-833-ENHERTU 9 AM to 6 PM ET,
(1-833-364-3788) Monday through Friday** **www.ENHERTU4U.com** **1-833-904-1851**

Please see Important Safety Information on pages 5-6, and see full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Application for patients prescribed ENHERTU to receive ENHERTU at no cost (cont'd)

PATIENT INFORMATION:

Name: _____ Date of Birth: ____ / ____ / ____
First *Middle Initial* *Last* *(MM/DD/YYYY)*

PRESCRIBER INFORMATION: *For completion by Prescriber*

This form will replace all previous prescriptions that may have been sent. All fields are required.

Prescriber Name: _____ Phone: (____) _____ Fax: (____) _____

Address: _____

City: _____ State: _____ ZIP: _____

Prescriber Email: _____ NPI: _____ State License Number (SLN): _____

Office Contact Name: _____ Phone: (____) _____ Practice Name: _____

Collaborating Physician Name (if applicable): _____

Administration Site: _____ Phone: (____) _____

Address: _____

Point of Contact Name: _____

PRESCRIPTION INFORMATION

HER2-positive or HER2-low metastatic breast cancer: The recommended dose of ENHERTU is 5.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. First infusion: Administer infusion over 90 minutes.

HER2-mutant metastatic non-small cell lung cancer (NSCLC): Due to increased toxicity at doses higher than 5.4 mg/kg in patients with NSCLC, including interstitial lung disease (ILD)/pneumonitis, the recommended dose of ENHERTU is 5.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. See ENHERTU Prescribing Information for further details. First infusion: Administer infusion over 90 minutes.

HER2-positive advanced gastric cancer: The recommended dose of ENHERTU is 6.4 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. First infusion: Administer infusion over 90 minutes.

ENHERTU® (fam-trastuzumab deruxtecan-nxki) Infuse _____ mg/kg IV over _____ minutes once every 3 weeks.
Patient weight: _____ kg 100 mg in single-dose vial quantity: _____ Refills: _____

SHIP MEDICATION TO PRESCRIBER ONLY.*

PLEASE NOTE: Medications cannot be shipped to Post Office (PO) boxes.

*(*For Prescribers in Ohio ONLY: Pursuant to OAC 4729-5-10, Ohio prescribers must be approved by the Ohio Board of Pharmacy to be a pick-up station)*

Sign Here ***Prescriber Signature:*** _____ ***Date:*** _____

Prescriber must comply with practicing state's specific prescription requirements, including but not limited to, electronic prescribing, state specific prescription form, etc. Noncompliance with state-specific requirements could result in outreach to prescriber by the pharmacy.

1-833-ENHERTU 9 AM to 6 PM ET,
(1-833-364-3788) Monday through Friday

www.ENHERTU4U.com

1-833-904-1851

CONSENT:

I GIVE my doctor and the Programs administrator and their employees, agents, and contractors permission to verify my information to make sure it is true and complete; contact me by mail or phone about the Programs and about other products, programs, or services that might interest me or for which I may be eligible; contact me in order to ensure that I have received the medicines sent by the Programs.

I PROMISE that all the information in this application, including all copies of documents proving my income, is true and complete; I am authorized to sign this application; I do not have any assistance or insurance that would help pay for my medicines (other than Medicare, if applicable); I will contact the Programs if any of my information about my prescription drug coverage or insurance changes.

I UNDERSTAND that the Programs will only use my information to decide if I qualify to participate in the Programs; administer or improve the Programs; communicate with insurance plans, including Medicare plans; share my information with the Centers for Medicare and Medicaid Services.

I UNDERSTAND that I may be required to apply for prescription assistance through a government assistance program to maintain eligibility in the Programs.

I UNDERSTAND that I can call 1-833-ENHERTU (1-833-364-3788) at any time to withdraw from the Programs and/or cancel my permission to use my information. I can visit https://dsi.com/privacy-notice to review Daiichi Sankyo's Privacy Notice.

I UNDERSTAND that the Programs can request more information from me at any time; ENHERTU4U can change or stop the Programs at any time or for any reason.

I UNDERSTAND that once my information has been disclosed to my doctor, federal privacy laws may no longer restrict its use or disclosure, but the Programs will only use my information as described in this form.

I MAY refuse to sign this authorization form and if I refuse, my eligibility for health plan benefits and treatment by my health care provider will not change, but I will not have access to the Programs.

I GIVE the Programs, and the Programs' administrators, permission to contact the person named below with follow-up questions about my application (this only applies if someone completed this application for you).

This authorization form will be effective for 1 year unless it expires earlier by law or I cancel it in writing. I have a right to receive a copy of this form after I have signed it.

What is the most important information I should know about ENHERTU?

ENHERTU can cause serious side effects, including:

Lung problems that may be severe, life-threatening or that may lead to death. If you develop lung problems your healthcare provider may treat you with corticosteroid medicines. Tell your healthcare provider right away if you get any of the following signs and symptoms:

- Cough
- Trouble breathing or shortness of breath
- Fever
- Other new or worsening breathing symptoms (e.g., chest tightness, wheezing)

Low white blood cell counts (neutropenia). Low white blood cell counts are common with ENHERTU and can sometimes be severe. Your healthcare provider will check your white blood cell counts before starting ENHERTU and before starting each dose. Tell your healthcare provider right away if you develop any signs or symptoms of an infection or have fever or chills during treatment with ENHERTU.

Heart problems that may affect your heart's ability to pump blood. Your healthcare provider will check your heart function before starting treatment with ENHERTU. Tell your healthcare provider right away if you get any of the following signs and symptoms:

- New or worsening shortness of breath
- Coughing
- Feeling tired
- Swelling of your ankles or legs
- Irregular heartbeat
- Sudden weight gain
- Dizziness or feeling light-headed
- Loss of consciousness

Your healthcare provider will check you for these side effects during your treatment with ENHERTU. Your healthcare provider may reduce your dose, delay treatment or completely stop treatment with ENHERTU if you have severe side effects.

Harm to your unborn baby. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with ENHERTU.

- If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ENHERTU.
- **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for 7 months after the last dose.
- **Males** who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with ENHERTU and for 4 months after the last dose.

Before you receive ENHERTU, tell your healthcare provider about all of your medical conditions, including if you:

- Have lung or breathing problems.
- Have signs or symptoms of an infection.
- Have or have had any heart problems.
- Are breastfeeding or plan to breastfeed. It is not known if ENHERTU passes into your breast milk. Do not breastfeed during treatment with ENHERTU and for 7 months after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive ENHERTU?

- You will receive ENHERTU into your vein through an intravenous (IV) line by your healthcare provider.
- ENHERTU is given 1 time every three weeks (21-day treatment cycle).
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will give you medicines before your infusion to help prevent nausea and vomiting.
- Your healthcare provider may slow down or temporarily stop your infusion of ENHERTU if you have an infusion-related reaction, or permanently stop ENHERTU if you have severe infusion reactions.
- If you miss a planned dose of ENHERTU, call your healthcare provider right away to schedule an appointment. Do not wait until the next planned treatment cycle.

What are the possible side effects of ENHERTU?

ENHERTU can cause serious side effects. See "What is the most important information I should know about ENHERTU?"

The most common side effects of ENHERTU, when used in people with metastatic breast cancer and HER2-mutant non-small cell lung cancer include:

- Nausea
- Low white blood cell counts
- Low red blood cell counts
- Feeling tired
- Low platelet counts
- Increased liver function tests
- Vomiting
- Hair loss
- Constipation
- Muscle or bone pain
- Decreased appetite
- Low levels of blood potassium
- Diarrhea
- Cough

The most common side effects of ENHERTU, when used in people with HER2-positive gastric or GEJ adenocarcinoma, include:

- Low red blood cell counts
- Low white blood cell counts
- Low platelet counts
- Nausea
- Decreased appetite
- Increased liver function tests
- Feeling tired
- Diarrhea
- Low levels of blood potassium
- Vomiting
- Constipation
- Fever
- Hair loss

ENHERTU may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of ENHERTU. Call your doctor for medical advice about side effects. You may report side effects to Daiichi Sankyo at 1-877-437-7763 or to FDA at 1-800-FDA-1088.

What is ENHERTU?

ENHERTU is a prescription medicine used to treat adults who have:

- Human epidermal growth factor receptor 2 (HER2)-positive breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received a prior anti-HER2 breast cancer treatment:
  - For metastatic disease, **or**
  - Have breast cancer that has come back during or within 6 months of completing treatment for their early-stage breast cancer.
- HER2-low breast cancer that cannot be removed by surgery or that has spread to other parts of your body (metastatic), and who have received a prior chemotherapy:
  - For metastatic disease, **or**
  - Your disease has returned during or within 6 months of completing adjuvant chemotherapy (after surgery). Your healthcare provider will perform a test to make sure ENHERTU is right for you.
- Non-small cell lung cancer (NSCLC) that has a certain mutation in the HER2 gene and cannot be removed by surgery or has spread to other parts of your body (metastatic), and who have received a prior treatment. Your healthcare provider will perform a test to make sure ENHERTU is right for you.

  ENHERTU was FDA approved for this use based on a clinical study that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results.
- Stomach cancer called gastric or gastroesophageal junction (GEJ) adenocarcinoma that is HER2-positive and has spread to areas near your stomach (locally advanced) or that has spread to other parts of your body (metastatic), and who have received a prior trastuzumab-based regimen.

It is not known if ENHERTU is safe and effective in children.

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

ENHERTU4U provides patients and their providers access and reimbursement support for ENHERTU. Reimbursement is not guaranteed. The ENHERTU Patient Assistance Program is limited to free medication only.

Daiichi-Sankyo | AstraZeneca