ENHERTU4U Enrollment Form

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

Support Requested (check only those that apply)

- ☐ Benefits Investigation (Please choose your preferred acquisition method below. Based on the preference, ENHERTU4U will research the pharmacy and/or medical benefits for your patient)
  - ☐ Buy & Bill
  - ☐ Specialty Pharmacy Provider (SPP). Preferred SPP: _____
  - ☐ Unknown
- ☐ Co-Pay Support (Note: You may also visit www.patientsavings4u.com for direct enrollment into the ENHERTU Patient Copay Savings Program (Eligibility rules apply)
- ☐ Prior Authorization Support
- ☐ Claims/Billing/Reimbursement Support (Please attach a copy of the claim submitted and Explanation of Benefits)
- ☐ Appeals Supports (Please attach a copy of the denial letter)

Please complete form, sign, and fax to **1-866-760-5917.**

For questions or assistance, please call ENHERTU4U, Monday through Friday, 8 AM – 6 PM ET, at **1-833-ENHERTU (1-833-364-3788)**.

To enroll in the ENHERTU Patient Assistance Program, visit www.ENHERTU4U.com/hcp/affordability. (Eligibility rules apply)

1 Patient Information

First Name: _____ Last Name: _____ Patient DOB: ___/___/___ Gender: ☐ M ☐ F

Address: _____ City: _____ State: _____ ZIP: _____

Preferred Phone #: ☐ Home ☐ Mobile _____ Patient Email: _____

Alternate Contact Name: _____ Relationship to Patient: _____

Alternate Contact Phone #: _____ Patient preferred language (if other than English): _____

Okay to contact patient? ☐ Yes ☐ No Okay to leave a detailed voicemail? ☐ Yes ☐ No

Patient Authorization

I have read and agree to the Patient Authorization included on page 2

_____ / / **Patient Signature/Legal Representative** MM DD YYYY

_____ **Printed Name/Relationship to Patient (if applicable)**

Support Programs (Savings Program and Additional Services)

I have read and agree to the Support Programs Authorization included on page 2

_____ / / **Patient Signature/Legal Representative** MM DD YYYY

_____ **Printed Name/Relationship to Patient (if applicable)**

2 Insurance Information

Please include front and back copies of all medical and pharmacy cards or complete this section.

☐ Commercial/Private Insurance ☐ Medicare/Medicaid/Tricare ☐ No insurance

	Primary Medical Insurance	Secondary Medical Insurance	Pharmacy Insurance
Insurance Provider			
Insurance Phone #			
Cardholder Name (if not the patient)			
Cardholder DOB			
Policy #			
Group #			
BIN/PCN	X	X	

3 Provider Information

Prescriber Name: _____ Specialty: _____

Practice Name: _____ Office Contact Name: _____

Address: _____ City: _____ State: _____ ZIP: _____

Phone #: _____ Fax #: _____ Email: _____

Prescriber NPI #: _____ Site Tax ID #: _____

PTAN: _____ Other Provider ID (if applicable): _____

Alternate Office Contact Name: _____ Alternate Office Contact Phone #: _____ Alternate Office Contact Email: _____

Please see Important Safety Information on pages 4-7, and see full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Patient Authorization

I authorize my health care providers (HCPs) and staff, my health plan, and my pharmacies to use and share Protected Health Information (my "Information") with AstraZeneca and Daiichi Sankyo (AZ/DSI) and its affiliates, as well as its contractors. My Information includes my prescription-related health records, Information about my health care plan benefits, demographic, contact, and any other Information bearing on my health. My Information may be used to verify treatment and payment decisions with my HCPs; investigate and assist with coordination of coverage for AZ/DSI Alliance Product; coordinate prescription fulfillment and financial assistance; and perform internal analysis at AZ/DSI to better meet patient needs. I understand and agree that AZ/DSI may contact me by mail, email, and telephone. I understand that federal privacy laws may not protect my Information once it is disclosed; however, AZ/DSI agrees to protect my Information by using and disclosing it only for purposes specified. I understand that I can refuse to sign this Authorization and that this will not affect my treatment or payment for treatment, insurance coverage, or eligibility for benefits. However, if I do not sign this Authorization, I will not be able to receive AZ/DSI Alliance Product support. I understand that I may cancel this Authorization at any time by calling **1-833-ENHERTU (1-833-364-3788)**. I understand that any such cancellation will not apply to any Information already used or disclosed based on this Authorization prior to their receipt of the cancellation. This Authorization expires two (2) years from the date signed, unless a shorter period is required by state law.

Support Programs Authorization

By providing consent, I understand that I may receive ongoing information and support related to my condition which includes, but is not limited to, providing me with educational and promotional materials, information, special offers, and services related to my medical condition or therapy, as well as for market research purposes which includes contacting me to participate in focus groups, surveys or interviews. This may include AZ/DSI or a third party working on AZ/DSI's behalf contacting me by mail, telephone, email and/or text message regarding AZ/DSI support programs that may be of interest to me. I consent to receive marketing and non-marketing calls and texts from and on behalf of AZ/DSI, made with an auto-dialer or prerecorded voice, at the phone number(s) provided. Message and data rates may apply. My Information may also be used to perform internal analysis at AZ/DSI. I understand that I can refuse to provide this Authorization and that this will not affect my treatment or payment for treatment, insurance coverage, or eligibility for benefits. I understand that my consent is not required or a condition of purchase. I understand that I may cancel this Authorization at any time by calling **1-833-ENHERTU (1-833-364-3788)** Information provided by AZ/DSI does not take the place of talking to your health care provider about your treatment or condition. AZ/DSI will not knowingly collect, use, or disclose personally identifiable information from a minor under the age of 18. If you are under the age of 18, please have your parent, guardian, or health care provider request the information on your behalf. Please visit https://dsi.com/privacy-notice to review our Privacy Notice.

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Patient First Name: _____

Patient Last Name: _____ **Patient DOB:** ____/____/____

4 Clinical Information

Diagnosis ICD-10 code(s): _____

By signing this form, I certify that (1) I have received the necessary authorization to release the information included on this form and other related Protected Health Information (as defined by HIPAA) to (DSI/AZ Alliance Programs), including employees, contractors, or affiliates of AstraZeneca/Daiichi Sankyo, and health care plans for programs, dispensing pharmacy(ies), or other entities, for the purposes of treatment and payment support; and (2) I have obtained any necessary authorization to allow (DSI/AZ Alliance Programs) to contact the patient, if not included with this submission, to obtain a signed (DSI/AZ Alliance Programs) Patient Authorization.

HCP Name: _____

HCP Signature: _____ Date: _____

5 Alternate Site of Care

If administering practice differs from provider practice, complete this section with administering practice information:

Practice Name: _____ Office Contact Name: _____

Phone #: _____ Fax #: _____ Site Tax ID #: _____ NPI #: _____

Place of Service Code: _____ Address: _____ City: _____ State: _____ ZIP: _____

6 Free Limited Supply

The Free Limited Supply program is available for eligible patients who are experiencing a coverage delay of more than 5 business days. Please complete the optional prescription below to help expedite access to ENHERTU in the case of a coverage delay.

ENHERTU® (fam-trastuzumab deruxtecan-nxki) _____

_____ 100 mg single-dose vial quantity: _____ No refills.

I verify that the information provided on this form is accurate. I understand that the patient must have an FDA-approved diagnosis to be eligible for free limited supply. I also understand I must submit a prescription compliant with my state law. Reimbursement for the cost of the product administered to the above patient on the date(s) indicated has not been sought and will not be sought from any source. Additionally, I understand that (DSI/AZ Alliance Programs) reserves the right to conduct periodic audits of the records, excluding patient-identifiable data (unless patient authorization is on file with (DSI/AZ Alliance Programs)), of all entities receiving free limited supply. I understand that (DSI/AZ Alliance Programs) reserves the right to modify or revoke this program at any time without notice. My signature confirms that this product was provided free of charge to this patient. (Using signature stamp or signing on behalf of the prescriber is not permitted.)

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

1-833-ENHERTU
(1-833-364-3788)

www.ENHERTU4U.com

1-866-760-5917

Please complete form, sign, and fax all pages to 1-866-760-5917.

ENHERTU4U provides patients and their providers access and reimbursement support for ENHERTU. Reimbursement is not guaranteed.

Important Safety Information

ENHERTU® 4U
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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 (such as chest tightness, wheezing)

- **Low white blood cell count (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 and during treatment if needed. 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.

Please see additional Important Safety Information on pages 4-7, and see full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

How will I receive ENHERTU?

- You will receive ENHERTU into your vein through an intravenous (IV) line by your healthcare provider.
- For the treatment of early breast cancer:
  - Before surgery, ENHERTU is given 1 time every three weeks (21-day treatment cycle) for 4 cycles followed by THP for 4 cycles.
  - After HER2-targeted treatment and surgery, ENHERTU is given 1 time every three weeks (21-day treatment cycle) for 14 cycles.
- For the treatment of metastatic breast cancer, HER2-mutant non-small cell lung cancer, gastric cancer or other HER2-positive solid tumors:
  - 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 alone at the 5.4 mg/kg dose in people with HER2-positive, HER2-Low and HER2-Ultralow breast cancer, HER2-mutant non-small cell lung cancer, and other HER2-positive solid tumors include:

- low white blood cell counts
- nausea
- low red blood cell counts
- feeling tired
- low platelet counts
- increased liver function tests
- vomiting
- hair loss
- constipation
- low levels of blood potassium
- decreased appetite
- diarrhea
- muscle or bone pain

The most common side effects of ENHERTU when used alone at the 5.4 mg/kg dose followed by THP, in people with HER2-positive stage II or stage III early breast cancer, include:

- low red blood cell counts
- increased liver function tests
- low white blood cell counts
- nausea
- inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs
- diarrhea
- hair loss
- feeling tired
- rash
- muscle or bone pain
- low levels of blood potassium
- constipation
- vomiting
- sores in or around your mouth
- decreased appetite

Please see additional Important Safety Information on pages 4-7, and see full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

The most common side effects of ENHERTU, when used in combination with pertuzumab at the 5.4 mg/kg dose in people with HER2-positive metastatic breast cancer include:

- low white blood cell counts
- low red blood cell counts
- nausea
- increased liver function tests
- diarrhea
- low platelet counts
- low levels of blood potassium
- feeling tired
- hair loss
- vomiting
- upper respiratory tract infection
- constipation
- decreased appetite
- weight loss
- COVID-19
- muscle or bone pain
- increased levels of blood bilirubin
- stomach pain

The most common side effects of ENHERTU, when used alone at the 6.4 mg/kg dose 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
- increased levels of blood bilirubin
- 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 with:

- Human epidermal growth factor receptor 2 (HER2)-positive stage II or stage III early breast cancer followed by a taxane, trastuzumab and pertuzumab (THP) before surgery. Your healthcare provider will perform a test to make sure ENHERTU is right for you.
- HER2-positive breast cancer that cannot be removed by surgery or has spread to other parts of the body (metastatic) in combination with pertuzumab as your first treatment. Your healthcare provider will perform a test to make sure ENHERTU in combination with pertuzumab is right for you.

ENHERTU alone is a prescription medicine used to treat adults with:

- HER2-positive early breast cancer who have received trastuzumab (with or without pertuzumab) and taxane-based treatment before surgery and have cancer remaining in the tissue removed during surgery.
- 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.

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- HER2-low 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 chemotherapy:
  - for metastatic disease, **or**
  - whose 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.
- Hormone receptor (HR)-positive, HER2-low or HR-positive, HER2-ultralow breast cancer that cannot be removed by surgery or that has spread to other parts of the body (metastatic), and who have received one or more endocrine treatments for metastatic disease. 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.
- solid tumors that are HER2-positive (IHC 3+) and that cannot be removed by surgery or have spread to other parts of your body (metastatic), and who have received a prior treatment and have no other satisfactory treatment options. Your healthcare provider will perform a test to make sure ENHERTU is right for you.
  - ENHERTU was FDA approved for this use based on clinical studies that measured how many patients responded and how long they responded. ENHERTU is still being studied to confirm these results.

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.

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