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
- ☐ Prior Authorization Support
- ☐ Specialty Pharmacy Coordination
- ☐ Claims/Billing/Reimbursement Support
  (Please attach a copy of the claim submitted and Explanation of Benefits)
- ☐ Appeals Support (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 – 8 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)

ENHERTU Patient Savings Program

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)

☐ Please check if you would like to receive marketing information and support related to your condition. Please see page 2 for more information.

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: _____

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 ENHERTU4U, 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 ENHERTU4U to contact the patient, if not included with this submission, to obtain a signed ENHERTU4U Patient Authorization.

HCP Name: _____

HCP Signature: _____ Date: _____

Please see Important Safety Information on page 4, and click here for full Prescribing Information, including Boxed WARNING, and click here for 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 ENHERTU; 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 ENHERTU4U support. I understand that I may cancel this Authorization at any time by calling **1-833-ENHERTU (1-833-364-3788)** or by mailing a letter requesting such cancellation to **Daiichi Sankyo at 211 Mt. Airy Road, Basking Ridge, NJ 07920-2311**. 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 on page 1, unless a shorter period is required by state law.

ENHERTU Patient Savings Program

The ENHERTU Patient Savings Program is designed to facilitate access to ENHERTU. By providing my Authorization, I allow my health care providers, insurance companies and pharmacies to use and share my health care Information with the ENHERTU Patient Savings Program so that I can participate in this savings program. My health Information may be seen by AZ/DSI and companies working on their behalf for this savings program.

Optional Services

I understand that I may also receive ongoing information and support related to my condition, including treatment information. This may include AZ/DSI, or a third party working on their behalf, contacting me regarding ENHERTU support programs that may be of interest to me. Information provided by AZ/DSI does not take the place of talking to your health care provider about your treatment or condition. AZ/DSI or third parties working on their behalf will not sell or rent your personal information. If, in the future, you no longer want to receive these materials or calls, or you want to report a medication side effect, please call **1-877-437-7763**. Please visit https://dsi.com/privacy-notice to review our Privacy Notice.

ENHERTU4U Enrollment Form

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

Patient First Name: _____

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

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.

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.

ENHERTU® (fam-trastuzumab deruxtecan-nxki) Infuse _____ mg/kg IV over 90 minutes.

Patient weight: _____ kg 100 mg in 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 ENHERTU4U reserves the right to conduct periodic audits of the records, excluding patient-identifiable data (unless patient authorization is on file with ENHERTU4U), of all entities receiving free limited supply. I understand that ENHERTU4U 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.)

7 Acquisition

☐ **Buy & Bill (Below prescription does not need to be completed)**

☐ **Specialty Pharmacy Provider (SPP) (Please select preferred SPP and complete prescription below)**

☐ Accredo ☐ Avella ☐ Biologics ☐ CVS Specialty ☐ Onco 360 ☐ No Preference*

**If you have questions about in-network SPP(s) for your patient, contact ENHERTU4U at 1-833-364-3788. By choosing "No Preference," the SPP will be chosen based on the results of a Benefits Investigation.*

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. Subsequent infusions: Administer over 30 minutes if prior infusions were well tolerated.

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: _____

I authorize ENHERTU4U to convey the attached prescription on my behalf to the pharmacy chosen above and to receive information on the status and related matters. By signing below, I certify that the medicine prescribed on this form is medically necessary based on my independent medical judgment, and I have received the necessary authorization to release the information included on this form and other Protected Health Information (as defined by HIPAA) to ENHERTU4U, the dispensing pharmacy, or other contractors for the purpose of seeking reimbursement or assisting in initiating or continuing therapy. Each practitioner is solely responsible for ensuring the accuracy of the information submitted.

8 Prescriber Signature

This prescriber signature applies to Sections 6 and 7.

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.

Please see Important Safety Information on page 4, and click here for full Prescribing Information, including Boxed WARNING, and click here for Medication Guide.

Important Safety Information

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

Indication

ENHERTU is a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

WARNING: INTERSTITIAL LUNG DISEASE and EMBRYO-FETAL TOXICITY

- **Interstitial lung disease (ILD) and pneumonitis, including fatal cases, have been reported with ENHERTU. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. Permanently discontinue ENHERTU in all patients with Grade 2 or higher ILD/pneumonitis. Advise patients of the risk and to immediately report symptoms.**
- **Exposure to ENHERTU during pregnancy can cause embryo-fetal harm. Advise patients of these risks and the need for effective contraception.**

Contraindications

None.

WARNINGS AND PRECAUTIONS

Interstitial Lung Disease / Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ENHERTU. In clinical studies, of the 234 patients with unresectable or metastatic HER2-positive breast cancer treated with ENHERTU, ILD occurred in 9% of patients. Fatal outcomes due to ILD and/or pneumonitis occurred in 2.6% of patients treated with ENHERTU. Median time to first onset was 4.1 months (range: 1.2 to 8.3).

Advise patients to immediately report cough, dyspnea, fever, and/or any new or worsening respiratory symptoms. Monitor patients for signs and symptoms of ILD. Promptly investigate evidence of ILD. Evaluate patients with suspected ILD by radiographic imaging. Consider consultation with a pulmonologist. For asymptomatic ILD/pneumonitis (Grade 1), interrupt ENHERTU until resolved to Grade 0, then if resolved in ≤28 days from date of onset, maintain dose. If resolved in >28 days from date of onset, reduce dose one level. Consider corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥0.5 mg/kg prednisolone or equivalent). For symptomatic ILD/pneumonitis (Grade 2 or greater), permanently discontinue ENHERTU. Promptly initiate corticosteroid treatment as soon as ILD/pneumonitis is suspected (e.g., ≥1 mg/kg prednisolone or equivalent). Upon improvement, follow by gradual taper (e.g., 4 weeks).

Neutropenia

Severe neutropenia, including febrile neutropenia, can occur in patients treated with ENHERTU. Of the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, a decrease in neutrophil count was reported in 30% of patients and 16% had Grade 3 or 4 events. Median time to first onset was 1.4 months (range: 0.3 to 18.2). Febrile neutropenia was reported in 1.7% of patients.

Monitor complete blood counts prior to initiation of ENHERTU and prior to each dose, and as clinically indicated. Based on the severity of neutropenia, ENHERTU may require dose interruption or reduction. For Grade 3 neutropenia (Absolute Neutrophil Count [ANC] <1.0 to 0.5 x 10^9/L) interrupt ENHERTU until resolved to Grade 2 or less, then maintain dose. For Grade 4 neutropenia (ANC <0.5 x 10^9/L) interrupt ENHERTU until resolved to Grade 2 or less. Reduce dose by one level. For febrile neutropenia (ANC <1.0 x 10^9/L and temperature >38.3ºC or a sustained temperature of ≥38ºC for more than 1 hour), interrupt ENHERTU until resolved. Reduce dose by one level.

Left Ventricular Dysfunction

Patients treated with ENHERTU may be at increased risk of developing left ventricular dysfunction. Left ventricular ejection fraction (LVEF) decrease has been observed with anti-HER2 therapies, including ENHERTU. In the 234 patients with unresectable or metastatic HER2-positive breast cancer who received ENHERTU, two cases (0.9%) of asymptomatic LVEF decrease were reported. Treatment with ENHERTU has not been studied in patients with a history of clinically significant cardiac disease or LVEF <50% prior to initiation of treatment.

Assess LVEF prior to initiation of ENHERTU and at regular intervals during treatment as clinically indicated. Manage LVEF decrease through treatment interruption. Permanently discontinue ENHERTU if LVEF of <40% or absolute decrease from baseline of >20% is confirmed. When LVEF is >45% and absolute decrease from baseline is 10-20%, continue treatment with ENHERTU. When LVEF is 40-45% and absolute decrease from baseline is <10%, continue treatment with ENHERTU and repeat LVEF assessment within 3 weeks. When LVEF is 40-45% and absolute decrease from baseline is 10-20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF has not recovered to within 10% from baseline, permanently discontinue ENHERTU. If LVEF recovers to within 10% from baseline, resume treatment with ENHERTU at the same dose. When LVEF is <40% or absolute decrease from baseline is >20%, interrupt ENHERTU and repeat LVEF assessment within 3 weeks. If LVEF of <40% or absolute decrease from baseline of >20% is confirmed, permanently discontinue ENHERTU. Permanently discontinue ENHERTU in patients with symptomatic congestive heart failure.

Embryo-Fetal Toxicity

ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. Verify the pregnancy status of females of reproductive potential prior to the initiation of ENHERTU. Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of ENHERTU. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months after the last dose of ENHERTU.

Adverse Reactions

The safety of ENHERTU was evaluated in a pooled analysis of 234 patients with unresectable or metastatic HER2-positive breast cancer who received at least one dose of ENHERTU 5.4 mg/kg in DESTINY-Breast01 and Study DS8201-A-J101. ENHERTU was administered by intravenous infusion once every three weeks. The median duration of treatment was 7 months (range: 0.7 to 31).

Serious adverse reactions occurred in 20% of patients receiving ENHERTU. Serious adverse reactions in >1% of patients who received ENHERTU were interstitial lung disease, pneumonia, vomiting, nausea, cellulitis, hypokalemia, and intestinal obstruction. Fatalities due to adverse reactions occurred in 4.3% of patients including interstitial lung disease (2.6%), and the following events occurred in one patient each (0.4%): acute hepatic failure/acute kidney injury, general physical health deterioration, pneumonia, and hemorrhagic shock.

ENHERTU was permanently discontinued in 9% of patients, of which ILD accounted for 6%. Dose interruptions due to adverse reactions occurred in 33% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose interruption were neutropenia, anemia, thrombocytopenia, leukopenia, upper respiratory tract infection, fatigue, nausea, and ILD. Dose reductions occurred in 18% of patients treated with ENHERTU. The most frequent adverse reactions (>2%) associated with dose reduction were fatigue, nausea, and neutropenia.

The most common adverse reactions (frequency ≥20%) were nausea (79%), fatigue (59%), vomiting (47%), alopecia (46%), constipation (35%), decreased appetite (32%), anemia (31%), neutropenia (29%), diarrhea (29%), leukopenia (22%), cough (20%), and thrombocytopenia (20%).

Use in Specific Populations

- **Pregnancy:** ENHERTU can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risks to a fetus. There are clinical considerations if ENHERTU is used in pregnant women, or if a patient becomes pregnant within 7 months following the last dose of ENHERTU.
- **Lactation:** There are no data regarding the presence of ENHERTU in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ENHERTU and for 7 months after the last dose.
- **Females and Males of Reproductive Potential:** Pregnancy testing: Verify pregnancy status of females of reproductive potential prior to initiation of ENHERTU. Contraception: *Females*: ENHERTU can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 7 months following the last dose. *Males*: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ENHERTU and for at least 4 months following the last dose. Infertility: ENHERTU may impair male reproductive function and fertility.
- **Pediatric Use:** Safety and effectiveness of ENHERTU have not been established in pediatric patients.
- **Geriatric Use:** Of the 234 patients with HER2-positive breast cancer treated with ENHERTU 5.4 mg/kg, 26% were ≥65 years and 5% were ≥75 years. No overall differences in efficacy were observed between patients ≥65 years of age compared to younger patients. There was a higher incidence of Grade 3-4 adverse reactions observed in patients aged ≥65 years (53%) as compared to younger patients (42%).
- **Hepatic Impairment:** In patients with moderate hepatic impairment, due to potentially increased exposure, closely monitor for increased toxicities related to the topoisomerase inhibitor.

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc. at 1-877-437-7763 or FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please click here for full Prescribing Information, including Boxed WARNING, and click here for Medication Guide.

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

Daiichi-Sankyo | AstraZeneca