Fast Track to Patient Access

EGRIFTA® Enrollment Form

1-833-23-THERA (1-833-238-4372),
Mon-Fri 8 AM - 8 PM EST
The EGRIFTA® Enrollment Form provides the prescription, and guidance on the clinical documentation needed to begin the reimbursement process for EGRIFTA®. It will also help to connect the patient with the Patient Care Coordinators. Download an electronic version of the EGRIFTA® enrollment form and a copy of the FAST Track Guide at THERApatientsupport.com

### Patient Information
In order for the Patient Care Coordinator to expedite the reimbursement process, **all of the information in this section must be recorded**. Have patients check that all relevant contact information is current and active. This includes the patient’s name, address, phone number, email, and alternate contact/caregiver information.

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<td>Gender</td>
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### Medical History
Report important medical history to support the case for EGRIFTA® reimbursement. **Information in this section needs to be filled out completely and accurately for the enrollment form to be processed quickly.**

- **Currently on anti-retroviral therapy (ART):** The use and length of time on ART is a factor in the development of excess visceral adipose tissue (VAT)\(^2\)
  - Patient must be on ART to be eligible to receive EGRIFTA®
- **Fasting Blood Glucose/BMI:** A fasting blood glucose level lower than 150 mg/dL is required by many plans for a patient to be eligible to receive EGRIFTA®\(^2\)
- **Waist Circumference/Waist-to-hip Ratio:** Measure and record the waist circumference and hip circumference to calculate the waist-to-hip ratio. Waist circumference and waist-to-hip ratio are indicators of excess abdominal VAT:\(^3\)
  - Waist circumference:
    - Men ≥37.4 in (95 cm)
    - Women ≥37 in (94 cm)
  - Waist-to-hip ratio:
    - Men ≥0.94
    - Women ≥0.88
- **Concomitant Medications:** Indicate all medications that the patient is currently taking

### Insurance Information
All information in this section must be recorded. Have the patient check that all relevant insurance information is current and active. This includes:

- If the patient does not have insurance, the Patient Care Coordinators will verify the patient’s available benefits and investigate any additional coverage for which they are eligible
- If the patient has insurance, be sure to include the following to expedite the processing of this form:
  - The prescription drug insurer/ pharmacy benefit manager (PBM) name, phone number, policy number, Rx number, Rx Group number, and Rx PCN number
  - A photocopy of the front and back of the patient’s insurance card(s)

### Prescription Information
This section, in conjunction with the Prescriber Authorization section, is the prescription for EGRIFTA®. In some cases, the pharmacy may contact you for a verbal authorization or written prescription. EGRIFTA® is only available through specialty pharmacies. A list of specialty pharmacies can be found on EGRIFTA.com. Please indicate:

- **EGRIFTA® with the pre-populated NDC number. This must be checked off for the enrollment form to be processed**
- **Diagnosis code (ICD-10): E88.1 HIV-Associated Lipodystrophy. This is pre-populated and must be checked off for the form to be processed**
- **Whether it is a monthly prescription with the appropriate refills or a 3-month prescription with the appropriate refills. An injection kit will be dispensed with the prescription**
  - If writing a prescription for more or less than 1 year, please check the “Other” box and fill in the appropriate number of refills
  - Any additional instructions, if necessary
  - A preferred specialty pharmacy, if desired

### Prescriber Authorization
This section, in conjunction with the Prescription Information section, functions as the prescription for EGRIFTA®. In some cases, the pharmacy may contact you for a verbal authorization or a written prescription. Since this is a prescription, please note that stamps are not permitted in place of an actual signature. You must sign and date one of the lines for the prescription to be filled. Use one of the following:

- **Dispense As Written:** Sign to indicate that EGRIFTA® should be filled and to prevent being switched by the pharmacy or health plan
- **Substitution Permissible:** Sign to indicate that a substitution for EGRIFTA® may be made by the pharmacy or health plan

Remember to fill out all sections and provide as much detail as possible.
THERA patient support™ provides patients with access to EGRIFTA®.

How THERA patient support™ works:

1. Enrolling EGRIFTA® patients

- The EGRIFTA® Enrollment Form needs to be completed by the prescribing physician and patient. Please ensure the following:
  - All required signatures are included
  - The form is signed and dated by the prescribing physician
  - The “Patient Authorization to Use and Disclose Protected Health Information” on the back of the form is signed and dated by the patient
  - The “Insurance Information” section, including the policy number and telephone number, is completely filled out
- Include additional documentation, such as photocopies of the patient’s insurance card(s)
- Fax completed enrollment form to 1-855-836-3069
- Each patient will be partnered with a dedicated Patient Care Coordinator, who will start the enrollment process. The Patient Care Coordinator may request additional information during the process.

2. Reimbursement Navigation and Financial Assistance

The Patient Care Coordinator will verify the patient’s available benefits and investigate any additional coverage for which they are eligible.

Privately-insured patients:

- THERA patient support™ coordinates coverage benefits with commercial insurers.
- Co-pay assistance for out-of-pocket costs may be available

Government-insured patients:

- THERA patient support™ coordinates coverage benefits with the appropriate provider
- THERA patient support™ can also advise on third-party assistance for out-of-pocket costs

Uninsured patients:

- THERA patient support™ investigates possible third-party coverage
- Some patients may be eligible for the EGRIFTA® Patient Assistance Program

THERA patient support™ will also assist in the Prior Authorization process. Additional enrollment forms can be found on EGRIFTA.com and completed electronically.

THERA patient support™ maintains regular contact with patients during their treatment. The Staff Nurses provide additional support, which may help promote adherence, by:

- Training patients on proper injection and reconstitution techniques
- Sharing advice for starting and staying on therapy
- Answering common therapy-related questions throughout their treatment
**IMPORTANT RISK INFORMATION FOR EGRIFTA® (TESAMORELIN FOR INJECTION)**

**Indication**

*EGRIFTA®* is indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

**Limitations of use:**

- The impact and safety of *EGRIFTA®* on cardiovascular health have not been studied.
- *EGRIFTA®* is not indicated for weight loss management.
- It is not known whether taking *EGRIFTA®* helps improve compliance with anti-retroviral medications.

**Contraindications:**

Do not use *EGRIFTA®* if you:

- Have pituitary gland tumor, pituitary gland surgery or other problems related to your pituitary gland.
- Have active cancer.
- Are allergic to tesamorelin or any of the ingredients in *EGRIFTA®*.
- Are pregnant.

**Warnings and Precautions**

- **Neoplasms:** Preexisting malignancy should be inactive and its treatment complete prior to starting *EGRIFTA®* therapy.
- **Elevated IGF-1:** Monitor regularly in all patients. Consider discontinuation in patients with persistent elevations (eg, >3 SDS).
- **Fluid Retention:** May include edema, arthralgia, and carpal tunnel syndrome.
- **Glucose Intolerance:** May develop with *EGRIFTA®* treatment. Evaluate glucose status prior to and during therapy with *EGRIFTA®*.
- **Hypersensitivity Reactions:** (e.g., rash, urticaria): Advise patients to seek immediate medical attention if suspected.
- **Injection Site Reactions:** Advise patients to rotate sites.
- **Acute Critical Illness:** *EGRIFTA®* has not been studied in patients with acute critical illness. Increased mortality in critically ill patients has been reported in patients treated with pharmacological doses of growth hormone. Since *EGRIFTA®* stimulates the production of growth hormone. Consider discontinuation in critically ill patients.

**Drug Interactions**

- *EGRIFTA®* had no significant impact on the pharmacokinetic profiles of simvastatin in healthy subjects. Monitor carefully when *EGRIFTA®* is administered in combination with other drugs known to be metabolized by CYP450.
- Patients on glucocorticoids may require dosage adjustment upon initiation of *EGRIFTA®*.

**Use in Specific Populations**

- **Nursing Mothers:** Because of both the potential for HIV-1 infection transmission and serious adverse reactions in nursing infants, mothers receiving *EGRIFTA®* should be instructed not to human breast-feed.
- **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.
- **Renal and Hepatic Impairment:** Use in renal and hepatic impairment have not been studied.
- **Geriatric Use:** There is no information on use in patients greater than 65 years of age.

**Adverse Reactions**

The most commonly reported adverse reactions: hypersensitivity reactions, arthralgia, injection site erythema, and injection site pruritus, pain in extremity, peripheral edema and myalgia.

For complete disclosure of *EGRIFTA®* product information, please read the Full Prescribing Information, Patient Information, and Patient Instructions for Use.

For more information about *EGRIFTA®*, contact THERA patient support™ toll-free at 1-833-23-THERA (1-833-238-4372). To report suspected adverse reactions, contact THERA patient support™ toll-free or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**References:**