EGRIFTA ASSIST®

1-844-EGRIFTA (1-844-347-4382)
Monday–Friday
from 8 AM to 8 PM EST

STATEMENT OF MEDICAL NECESSITY

To help HIV-infected patients with excess abdominal fat obtain *EGRIFTA®* through *EGRIFTA ASSIST®*, **you need to fax this completed form and the accompanying PATIENT AUTHORIZATION** to:

FAX: 1-855-836-3069

EGRIFTA® is only available through specialty pharmacies.

EGRIFTA® tesamorelin for injection

All information is required unless otherwise noted.

Physician and Practice Information

Name _____

Office/Clinic/Institution _____

Street Address _____

City _____ State _____ Zip _____

Phone # _____ Fax _____

NPI # _____ Tax ID# _____ DEA# _____

Medicaid # _____

Email Address (optional) _____

Office Contact

Name _____ Phone # _____

Medical History

The patient is currently receiving anti-retroviral therapy (ART) ❑ YES ❑ NO

Please provide the patient's:

Blood Fasting Glucose _____ mg/dL BMI _____ kg/m^2

Waist Circumference _____ cm Hip Circumference _____ cm

Waist-to-hip Ratio _____

NOTE: Waist-to-hip ratio can be important for payor approval. Please use this formula: Waist-to-hip ratio = Waist Circumference ÷ Hip Circumference

Would the patient benefit from injection training? ❑ YES ❑ NO

NOTE: Patients who can benefit from injection training will receive a phone call to help guide them through the self-administration process. Additionally, patients may call EGRIFTA ASSIST® with medically related questions or visit EGRIFTA.com to view an instructional administration video.

Patient's Personal Information

Name _____

Date of Birth _____

Gender ❑ Male ❑ Female Last 4 Digits of SS# (optional) _____

Street Address _____

City _____ State _____ Zip _____

Primary Phone # _____

Cell Phone # (optional) _____

Email Address (optional) _____

By providing your name, email address, or other personal information, you are giving Theratechnologies Inc. and companies working on our behalf permission to communicate with you about *EGRIFTA®* via mail, email, phone, or text. We will not sell or transfer your name, street address, or other personally identifiable information about you to any party for its own marketing use.

Insurance Information

Diagnosis _____ Diagnosis Code _____

The ICD-10 code for excess abdominal fat in HIV patients with lipodystrophy (the indication for *EGRIFTA®*) is E88.1.

NOTE: Without providing the above diagnosis and diagnosis code, this form cannot be processed.

Primary Insurance _____

Insurance ID _____

❑ **Copy of front and back of insurance card included**

NOTE: Prescriptions cannot be processed unless copies of both sides of the insurance card are included.

For Office Use Only

EGRIFTA ASSIST® Patient ID# _____

Please see Important Safety Information for *EGRIFTA®* on pages 3 and 4.

Rx and Statement of Medical Necessity to be Completed and Signed by Physician

Prescription: ❑ *EGRIFTA®* (tesamorelin for injection) with injection kit

Ship to: ❑ Home ❑ Physician's Office

Number of Refills _____

Pharmacy Strength: ❑ *EGRIFTA®* 1 mg/vial Quantity _____

Dosage and Directions for Use: 2 mg subcutaneous injection daily (requires 2 vials of *EGRIFTA®*, 1 mg each)

Additional Instructions _____

Preferred Specialty Pharmacy (optional) _____

Physician Certification: I certify that the prescribed therapy is medically necessary, that the information in this Statement of Medical Necessity is accurate to the best of my knowledge, and that I am aware of the risks and benefits associated with the use of *EGRIFTA®*. I authorize Theratechnologies Inc. (1) to provide any information on this form to the insurer of the named patient and (2) forward the above prescription.

Name _____ Date _____ Signature _____

NOTE: Physician needs to sign and date in order for the prescription to be filled.

Visit EGRIFTA.com to download copies of this form.

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Information to be Completed and Signed by Patient

Name _____ Street Address _____

Primary Phone # _____ Cell Phone # (optional)_____

Date of Birth _____

Authorization to Use and Disclose Protected Health Information

I authorize health care providers and their staff involved in my care to disclose my Protected Health Information (as hereafter defined), including but not limited to my medical record and other health information on my completed Statement of Medical Necessity form or other forms, records that may contain information created by other persons or entities, including physicians and other health care providers, as well as information regarding the use of drug and alcohol treatment services, confidential HIV/AIDS treatment, including HIV test results, and mental health services (excluding psychotherapy notes) (collectively, "Protected Health Information"), to Theratechnologies Inc. and its agents and representatives (collectively, "Theratechnologies"), so that Theratechnologies may, among other things:

(1) facilitate the filling of my prescription for and the delivery and administration of *EGRIFTA*®;

(2) assist me in obtaining insurance coverage for *EGRIFTA*®;

(3) contact me by mail, email, and/or telephone to enroll me in, and administer, programs that provide *EGRIFTA*® support services;

(4) provide me with free educational information and materials; and

(5) conduct surveys to measure my satisfaction with *EGRIFTA*® and *EGRIFTA*® support services.

I understand that once my Protected Health Information is disclosed pursuant to this authorization, it may no longer be protected by the federal privacy law and regulations known as "HIPAA" or state privacy laws and may be subject to further disclosure by Theratechnologies and other third parties with whom Theratechnologies may share the information. However, other state and federal laws may prohibit the recipient from disclosing specially protected information such as substance abuse treatment information, HIV/AIDS-related information, and psychiatric/mental health information.

I understand that I may refuse to sign this authorization and such refusal will not affect my ability to receive *EGRIFTA*®, but it may limit my ability to receive certain support services for *EGRIFTA*® that are provided by Theratechnologies.

I understand that health care providers may receive compensation as a result of their disclosure of my Protected Health Information as described herein.

I understand that this authorization will remain in effect for 10 years from the date of my signature, unless I revoke it in writing earlier by contacting Theratechnologies c/o inVentiv Health, 500 Atrium Drive, Somerset, NJ 08873.

If I revoke this authorization, health care providers will stop using and disclosing my information for the purposes outlined herein as soon as possible, but the revocation will not affect prior use or disclosure of my information in reliance on this authorization, and my revocation will have no effect on any third parties who may have received my Protected Health Information pursuant to this authorization, including Theratechnologies.

I understand that the support services provided by Theratechnologies that are described in this authorization can be changed at any time, without prior notification.

I have the right to receive a copy of this authorization.

_____ _____

Patient Name or Authorized Representative (please print) Date

_____

Patient Signature

If Authorized Representative please state basis for authority:

_____

NOTE TO RECIPIENT OF INFORMATION:

HIV Related Information: To the extent that HIV-related information has been provided to you, such information has been disclosed to you from records whose confidentiality may be protected by federal and state law. Such laws may prohibit you from making any further disclosure of the HIV-related information without the specific written consent of the person to whom it pertains, or as otherwise permitted by said laws. When obtaining such written consent, you must expressly identify that HIV-information is being disclosed (a general authorization for the release of the entire medical file, for example, is **NOT** sufficient for this purpose). An oral disclosure shall be accompanied or followed by such notice within ten days.

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SAFETY INFORMATION

EGRIFTA® tesamorelin for injection

Indication and Important Risk Information for *EGRIFTA®*

Indication

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

Limitations of Use:

- Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of *EGRIFTA®* treatment have not been studied and are not known, careful consideration should be given whether to continue *EGRIFTA®* treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan
- *EGRIFTA®* is not indicated for weight loss management (weight neutral effect)
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking *EGRIFTA®*

Contraindications

- Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism or pituitary tumor/surgery, head irradiation or head trauma
- Active malignancy (either newly diagnosed or recurrent). Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with *EGRIFTA®*
- Known hypersensitivity to tesamorelin and/or mannitol
- Women who are pregnant; if pregnancy occurs during treatment, discontinue *EGRIFTA®* therapy

Warnings and Precautions

Neoplasms: *EGRIFTA®* induces the release of endogenous growth hormone (GH), a known growth factor. Thus, patients with active malignancy should not be treated with *EGRIFTA®*. For patients with a history of non-malignant neoplasms, *EGRIFTA®* therapy should be initiated after careful evaluation of the potential benefit of treatment. For patients with a history of treated and stable malignancies, *EGRIFTA®* therapy should be initiated only after careful evaluation of the potential benefit of treatment relative to the risk of re-activation of the underlying malignancy. In addition, the decision to start treatment with *EGRIFTA®* should be considered carefully based on the increased background risk of malignancies in HIV-positive patients.

Elevated IGF-1: *EGRIFTA®* stimulates GH production and increases serum IGF-1. Given that IGF-1 is a growth factor and the effect of prolonged elevations in IGF-1 levels on the development or progression of malignancies is unknown, IGF-1 levels should be monitored closely during *EGRIFTA®* therapy. Careful consideration should be given to discontinuing *EGRIFTA®* in patients with persistent elevations of IGF-1 levels (eg, >3 SDS), particularly if the efficacy response is not robust (eg, based on visceral adipose tissue changes measured by waist circumference or CT scan). During the clinical trials, patients were monitored every three months. Among patients who received *EGRIFTA®* for 26 weeks, 47.4% had IGF-1 levels greater than 2 standard deviation scores (SDS), and 35.6% had SDS >3, with this effect seen as early as 13 weeks of treatment. Among those patients who remained on *EGRIFTA®* for a total of 52 weeks, at the end of treatment 33.7% had IGF-1 SDS >2 and 22.6% had IGF-1 SDS >3.

Fluid Retention: Fluid retention may occur during *EGRIFTA®* therapy and is thought to be related to the induction of GH secretion. It manifests as increased tissue turgor and musculoskeletal discomfort resulting in a variety of adverse reactions (eg, edema, arthralgia, carpal tunnel syndrome) which are either transient or resolve with discontinuation of treatment.

Glucose Intolerance: *EGRIFTA®* treatment may result in glucose intolerance. Patients treated with *EGRIFTA®* are at an increased risk of developing diabetes (HbA1c ≥ 6.5%). In clinical trials at week 26, a greater percentage of patients had elevated HbA1c (≥6.5%) in the *EGRIFTA®* group than in the placebo group (4.5% vs 1.3%). Glucose status should be carefully evaluated prior to initiating *EGRIFTA®* treatment and monitored periodically for changes in glucose metabolism to diagnose those who develop impaired glucose tolerance or diabetes. Caution should be exercised in treating patients with *EGRIFTA®* if they develop these conditions and discontinuation of treatment should be considered in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue by waist circumference or CT scan measurements. Since *EGRIFTA®* increases IGF-1, patients with diabetes who are receiving ongoing treatment with *EGRIFTA®* should be monitored at regular intervals for potential development or worsening of retinopathy.

Hypersensitivity Reactions: Hypersensitivity reactions may occur in patients treated with *EGRIFTA®*. Hypersensitivity reactions occurred in 3.6% of patients with HIV-associated lipodystrophy treated with *EGRIFTA®* in the Phase 3 clinical trials. These reactions included pruritus, erythema, flushing, urticaria, and other rash. In cases of suspected hypersensitivity reactions, patients should be advised to seek prompt medical attention and treatment with *EGRIFTA®* should be discontinued immediately.

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SAFETY INFORMATION

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Important Risk Information for *EGRIFTA*® (*continued*)

Injection-Site Reactions: *EGRIFTA*® treatment may cause injection-site reactions, including injection-site erythema, pruritus, pain, irritation, and bruising. The incidence of injection-site reactions was 24.5% in *EGRIFTA*®-treated patients and 14.4% in placebo-treated patients during the first 26 weeks of treatment in the Phase 3 clinical trials. For patients who continued *EGRIFTA*® for an additional 26 weeks, the incidence of injection-site reactions was 6.1%. In order to reduce the incidence of injection-site reactions, it is recommended to rotate the site of injection to different areas of the abdomen.

Acute Critical Illness: Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic amounts of growth hormone. *EGRIFTA*® has not been studied in patients with acute critical illness. Since *EGRIFTA*® stimulates growth hormone production, careful consideration should be given to discontinuing *EGRIFTA*® in critically ill patients.

Adverse Reactions

- The most commonly reported adverse reactions are hypersensitivity (eg, rash, urticaria) reactions due to the effect of GH (eg, arthralgia, extremity pain, peripheral edema, hyperglycemia, carpal tunnel syndrome), injection-site reactions (injection-site erythema, pruritus, pain, urticaria, irritation, swelling, hemorrhage)
- During the first 26 weeks of treatment (main phase), discontinuations as a result of adverse reactions occurred in 9.6% of patients receiving *EGRIFTA*® and 6.8% of patients receiving placebo. Apart from patients with hypersensitivity reactions identified during the studies and who were discontinued per protocol (2.2%), the most common reasons for discontinuation of *EGRIFTA*® treatment were adverse reactions due to the effect of GH (4.2%) and local injection-site reactions (4.6%)
- During the following 26 weeks of treatment (extension phase), discontinuations as a result of adverse events occurred in 2.4% of patients in the T–T group (patients treated with tesamorelin for Week 0-26 and with tesamorelin for Week 26-52) and 5.2% of patients in the T–P group (patients treated with tesamorelin for Week 0-26 and with placebo for Week 26-52)

Immunogenicity

Antibody formation may occur with the use of therapeutic peptide products. Anti-tesamorelin IgG antibodies were detected in approximately half of patients treated with *EGRIFTA*® and generally disappeared over time after discontinuation of treatment. Antibodies did not appear to impact the efficacy of *EGRIFTA*®.

Drug Interactions

Cytochrome P450-Metabolized Drugs: Co-administration of *EGRIFTA*® with simvastatin, a sensitive CYP3A substrate, showed that *EGRIFTA*® had no significant impact on the pharmacokinetic profiles of simvastatin in healthy subjects. Because tesamorelin stimulates GH production, careful monitoring is advisable when *EGRIFTA*® is administered in combination with other drugs known to be metabolized by CYP450 liver enzymes.

For information about additional drug interactions, please refer to the provided full Prescribing Information.

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 milk-feed. It is not known whether *EGRIFTA*® is excreted in human milk.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established. *EGRIFTA*® should not be used in children with open epiphyses, among whom excess GH and IGF-1 may result in linear growth acceleration and excessive growth.

Geriatric Use: There is no information on the use of *EGRIFTA*® in patients greater than 65 years of age with HIV and lipodystrophy.

Renal and Hepatic Impairment: Safety, efficacy, and pharmacokinetics of *EGRIFTA*® in patients with renal or hepatic impairment have not been established.

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

For more information about *EGRIFTA*®, please visit EGRIFTA.com or contact the *EGRIFTA ASSIST*® program toll-free at 1-844-EGRIFTA (1-844-347-4382).

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