THERA patient support®

EGRIFTA SV® tesamorelin for injection

Letter of Medical Necessity for *EGRIFTA SV®* (tesamorelin for injection)

Date: _____

Payer Name: _____

Payer Address: _____

City, State, Zip Code: _____

Payer Phone: _____

Payer Fax Number: _____

Patient Name: _____

Patient Date of Birth: _____

Policy Number: _____

Group Number: _____

Dear ,

I am writing on behalf of my patient, , to document the medical necessity of *EGRIFTA SV®* (2.0 mg/vial). This letter provides information about the patient's medical history, diagnosis, and a statement summarizing my treatment rationale.
EGRIFTA SV® is indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. *EGRIFTA SV®* is not indicated for weight loss, and its impact and safety on cardiovascular health have not been studied. It is not known if taking *EGRIFTA SV®* helps improve compliance with anti-retroviral medications. For additional safety information, please see page 4.

Patient History and Diagnosis

Use the Patient History and Diagnosis Guidelines on the last page of this form to ensure you include the information required by the health insurance plan.

Treatment Rationale

The following is a description of the treatment up to this point, the course of care, why the treatment/medication is necessary, and how it will help the patient:

To conclude, *EGRIFTA SV®* (2.0 mg/vial) is medically necessary for this patient's condition. Please contact me if any additional information is required to ensure the prompt approval of *EGRIFTA SV®*.

Sincerely,

Physician's Name

Physician's Practice Name

Enclosures

Indication

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

Limitations of Use

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

Contraindications

Do not use *EGRIFTA SV®* if patient:

- Has a pituitary gland tumor, has had pituitary gland surgery, has other problems related to their pituitary gland, or has had radiation treatment to their head or a head injury.
- Has active cancer.
- Is allergic to tesamorelin or any of the ingredients in *EGRIFTA SV®*.
- Is pregnant or planning to become pregnant.

Warnings and Precautions

- **Increased risk of neoplasms**: Preexisting malignancy should be inactive, and its treatment complete prior to starting *EGRIFTA SV®*. *EGRIFTA SV®* should be discontinued if the patient has evidence of recurrent malignancy.
- **Elevated IGF-1**: Monitor regularly IGF-1 levels in all patients during *EGRIFTA SV®* therapy. Consider discontinuing in patients with persistent elevations (e.g., >3 SDS).
- **Fluid retention**: May include edema, arthralgia, and carpal tunnel syndrome.
- **Glucose intolerance or diabetes mellitus**: May develop with *EGRIFTA SV®* use. Evaluate glucose status prior to and during therapy with *EGRIFTA SV®*.
- **Hypersensitivity reactions**: Advise patients to seek immediate medical attention and discontinue treatment if suspected.
- **Injection site reactions**: Advise patients to rotate injection sites to different areas of the abdomen to decrease injection site reactions.
- **Increased mortality in patients with acute critical illness**: Consider discontinuation in critically ill patients.

Drug Interactions

- *EGRIFTA SV®* had no significant impact on the pharmacokinetic profiles of simvastatin in healthy subjects.
- Monitor patients for potential interactions when administering *EGRIFTA SV®* in combination with other drugs known to be metabolized by CYP450 liver enzyme.
- Patients on glucocorticoids may require dosage adjustment upon initiation of *EGRIFTA SV®*.

Use in Specific Populations

- **Lactation**: Mothers should not breastfeed if they receive *EGRIFTA SV®*.
- **Pediatric Use**: Safety and effectiveness in pediatric patients have not been established.
- **Geriatric Use**: There is no information on the use of *EGRIFTA SV®* in patients greater than 65 years of age.
- **Renal and Hepatic Impairment**: Use in renal and hepatic impairment has not been studied.

Adverse Reactions

The most commonly reported adverse reactions include injection site reactions, arthralgia, pain in extremity, myalgia, and peripheral edema.

For a complete disclosure of *EGRIFTA SV®* product information, please read the Full Prescribing Information, Patient Information, and Patient Instructions for Use available at www.egriftasv.com.

For more information about *EGRIFTA SV®*, contact THERA patient support® toll-free at 1-833-23THERA (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.

Additional Enclosures

List any additional enclosures you have attached to this letter, including patient information such as clinical notes, diagnosis, viral load, CD4, and supporting CT scans (if available).

References

Include relevant references and publications regarding medication.

US-ESV-23**XXXXX**

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Patient History and Diagnosis Guidelines

Use this checklist to help ensure you provide the information required by the health insurance plan regarding the patient's history and diagnosis on pages 1–3.

- ☐ Explain why you believe it is medically necessary for the patient to receive this medicine.
- ☐ Provide documentation demonstrating the clinical diagnosis of HIV infection, the diagnosis of HIV-associated lipodystrophy, and the risk for medical complications due to excess abdominal fat.
- ☐ Provide documentation demonstrating that the patient has an excess accumulation of abdominal fat due to HIV-associated lipodystrophy, and meets the baseline waist circumference:
    - o If the patient is male: Waist circumference > 37.4 inches (95 cm) AND has a waist-to-hip ratio > 0.94.
    - o If the patient is female: Waist circumference > 37 inches (94 cm) AND has a waist-to-hip ratio > 0.88.
- ☐ Provide documentation demonstrating the patient's body mass index is > 20 kg/m^2 and the patient's fasting blood glucose is < 150 mg/dL (8.33 mmol/L).
- ☐ Attest that the patient does not have an active malignancy, either newly diagnosed or recurrent. Any pre-existing malignancy should be inactive, and its treatment complete prior to therapy with *EGRIFTA SV®*.
- ☐ If the patient is a woman of childbearing age, provide documentation for a negative pregnancy test.
- ☐ Provide documentation/attestation that the patient is on a stable regimen of highly active antiretroviral therapy for at least 8 weeks (including protease inhibitors, nucleoside reverse transcriptase inhibitors [NRTI], or non-nucleoside reverse transcriptase inhibitors [NNRTI]).
- ☐ Provide documentation for baseline labs (pre-treatment) and confirm that you will continue to monitor the patient during therapy for submission at the time of re-authorization request. Note that the following will be required for the continuation of therapy:
    - o Serum IGF level: Serum IGF-1 levels should be monitored at baseline and during therapy due to the potential risk of malignancy from sustained elevation of IGF-1 levels. In the absence of data or guidelines to support drug management in the setting of IGF-1 elevations, it is suggested to monitor IGF-1 at least every 6 months and aim to keep IGF-1 within the normal range of the assay used AND
    - o Serum glucose status: May increase risk of development of diabetes due to glucose intolerance. Monitor the patient periodically for glucose metabolism changes AND
    - o Retinopathy: Retinopathy patients with diabetes should be monitored for the development or worsening of retinopathy due to increased IGF levels.
- ☐ Describe the potential consequences if the patient does not receive this medicine.
- ☐ Include a list of previously used treatments, including any lifestyle medication programs.
- ☐ Obtain and attach supporting letters from any other (infectious disease) specialist(s) that is currently or has previously provided care to the patient.
- ☐ Provide documentation detailing any hospitalizations, emergency room/urgent care visits, or unscheduled visits due to their condition.

Once you have filled the Patient History and Diagnosis section of this form and are ready to submit to the patient's health insurance plan, delete this page.

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