THERA patient support®

EGRIFTA SV® tesamorelin for injection

Letter of Appeal 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 this letter to appeal the denial of coverage for *EGRIFTA SV®* (2.0 mg/vial) on behalf of my patient, . *EGRIFTA SV®* (2.0 mg/vial) is indicated for the reduction of excess abdominal fat in HIV-infected 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. Additional safety information can be found on page 3 of this letter.

On , your organization cited

as the reason for the denial of coverage. However, based on the FDA-approved indication, I strongly believe that treatment with *EGRIFTA SV®* (2.0 mg/vial) is medically necessary.

The following details explain why *EGRIFTA SV®* (2.0 mg/vial) is medically necessary for this patient, reinforces the points made in the Letter of Medical Necessity, and provides details about my credentials and experience treating patients with this condition.

In summary, based on my clinical opinion, *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®* (2.0 mg/vial).

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-2300031

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THERA technologies

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