Letter of Appeal

Date: _____

Payer Name: _____

Payer Address: _____

City: _____ State: _____ ZIP Code: _____

Payer Phone Number: _____ Payer Fax Number: _____

Patient Name: _____

Patient Date of Birth: _____

Policy Number: _____

Group Number: _____

Dear Appeals Department,

We are submitting this appeal to request coverage for *EGRIFTA WR™* (tesamorelin for injection, 11.6 mg/vial) for the above-referenced patient diagnosed with HIV-associated lipodystrophy (ICD-10: B20 and E88.14.

The impact and safety of *EGRIFTA WR™* on long-term cardiovascular health has not been studied. *EGRIFTA WR™* is not indicated for weight loss management. It is not known whether taking *EGRIFTA WR™* helps to improve compliance with anti-retroviral therapies in people with HIV. Additional Safety Information can be found on page 4 of this letter.

On , your organization cited

as the reason for the denial of coverage.

Due to limited inventory on hand, ongoing manufacturing challenges, and delays at our contract manufacturer, *EGRIFTA SV®* will no longer be available. The patient is currently maintained on *EGRIFTA SV®*, which is similar to *EGRIFTA WR™*. Both formulations contain the same active ingredient (tesamorelin) and demonstrate comparable pharmacokinetic properties, therefore same efficacy and safety, as confirmed by FDA approval of the new formulation on March 25, 2025. Both products are FDA-approved for the reduction of excess abdominal fat in patients with HIV with lipodystrophy.

Continuation of tesamorelin therapy—regardless of formulation—is medically necessary for this patient. Abrupt interruption of therapy may lead to recurrence of excess visceral adipose tissue accumulation, negatively affecting metabolic and psychological health related to body image and treatment adherence. Allowing substitution to *EGRIFTA WR™* ensures continuity of care and maintains therapeutic stability while supply issues persist.

We respectfully request that the plan approve coverage for the currently available formulation – *EGRIFTA WR™* – to avoid treatment disruption. Both products are therapeutically equivalent and clinically appropriate during this shortage.

On the next pages, you will find my recent office visit notes to support the diagnosis codes of B20 and E88.14, as well as additional resources for consideration.

Additional supporting documentation, including prescribing information and clinical notes, can be provided upon request. Please contact our office at or if additional information is required.

Recent office visit/clinic notes to support the patient's medical history and diagnosis of HIV (B20) and HIV-associated lipodystrophy (E88.14):

Resources for Consideration:

Enclosures

In summary, based on my clinical opinion, *EGRIFTA WR*™ (11.6 mg/vial) is medically necessary for this patient's condition. Both *EGRIFTA SV*® and *EGRIFTA WR*™ contain tesamorelin as the active ingredient and are FDA-approved for the same indication. The transition from *EGRIFTA SV*® to *EGRIFTA WR*™ is due solely to a manufacturer-driven supply change, not a change in therapy.

Please contact me if any additional information is required to ensure the prompt approval of *EGRIFTA WR*™ (11.6 mg/vial).

Thank you for your time and consideration.

Sincerely,

Practice Name:

NPI:

Phone:

Fax:

Additional Enclosures:

IMPORTANT SAFETY INFORMATION ABOUT *EGRIFTA WR*™ (TESAMORELIN) FOR INJECTION

Indication
EGRIFTA WR™ 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 WR*™ on cardiovascular health has not been studied.
- *EGRIFTA WR*™ is not indicated for weight loss management.
- It is not known whether taking *EGRIFTA WR*™ helps improve compliance with anti-retroviral medications.

Contraindications
Do not use *EGRIFTA WR*™ 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 WR*™.
- 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 WR*™. *EGRIFTA WR*™ should be discontinued if the patient has evidence of recurrent malignancy.
- **Elevated IGF-1**: Regularly monitor IGF-1 levels in all patients during *EGRIFTA WR*™ 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 WR*™ treatment. Evaluate glucose status prior to and during therapy with *EGRIFTA WR*™.
- **Hypersensitivity reactions**: Advise patients to seek immediate medical attention if suspected.
- **Injection site reactions**: Advise patients to rotate 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 WR*™ had no significant impact on the pharmacokinetic profiles of simvastatin in healthy subjects.
- Monitor patients for potential interactions when administering *EGRIFTA WR*™ in combination with other drugs known to be metabolized by CYP450 liver enzyme.
- Patients on glucocorticoids may require dosage adjustment upon initiation of *EGRIFTA WR*™.

Use in Specific Populations
- **Lactation**: Mothers should not breastfeed if they receive *EGRIFTA WR*™.
- **Pediatric use**: Safety and effectiveness in pediatric patients have not been established.
- **Geriatric use**: There is no information on the use of *EGRIFTA WR*™ in patients greater than 65 years of age.

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

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

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

US-F8-2500068