Letter of Appeal for ***EGRIFTA WR***™ **(Tesamorelin) for Injection**

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,

I am writing this letter to appeal the denial of coverage for *EGRIFTA WR*™ (11.6 mg/vial) on behalf of my patient, . *EGRIFTA WR*™ is indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. 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. Additional Safety Information can be found on page 4 of this letter.

On , your organization cited

as the reason for the denial of coverage.

Based on the **FDA-approved indication** and my clinical expertise, I strongly believe that **treatment with *EGRIFTA WR*™ (11.6 mg/vial) is medically necessary for this patient. The following details explain the medical necessity of *EGRIFTA WR*™ (11.6 mg/vial) for this patient's treatment.**

There is NO alternative or augmentative medication in this drug class to treat HIV-associated lipodystrophy (E88.1). *EGRIFTA WR*® is the ONLY FDA-approved treatment for E88.1.

On the 2 next pages, you will find, **my recent office visit notes to support the patient's diagnosis codes of B20 and E88.1**, and some resources for consideration.

Recent office visit/clinic notes to support the patient's medical history and diagnosis of HIV (B20) and HIV-associated lipodystrophy (E88.1):

Resources for Consideration:

1. EGRIFTA WR™ Prescribing Information, which includes the FDA indication and trial studies: URL TBD
2. Peer-reviewed literature supporting the efficacy of EGRIFTA® with this patient population:
• Koethe, J.R., Lagathu, C., Lake, J.E. et al. HIV and antiretroviral therapy-related fat alterations. Nat Rev Dis Primers 6, 48 (2020). [DOI: https://doi.org/10.1038/s41572-020-0181-1].

Include any other relevant references and publications regarding this medication.

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).

In summary, based on my clinical opinion, *EGRIFTA WR*™ (11.6 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 WR*™ (11.6 mg/vial).

Sincerely,

Physician's Name

Physician's Practice Name

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.

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