THERA patient support®

EGRIFTA WR™ (tesamorelin) for injection

Prior Authorization Checklist for *EGRIFTA WR*™ (Tesamorelin) for Injection

Your patient's health insurance plan may require **prior authorization (PA)** before approving *EGRIFTA WR*™ (11.6 mg/vial). When submitting a PA request for *EGRIFTA WR*™, use this checklist to ensure you provide the essential information requested by the health insurance plan.

Note that PA requirements vary, so check with your patient's health insurance plan to ensure you have included all the necessary components before submission.

The information provided on this checklist is general in nature and is not intended to be exhaustive. As the patient's healthcare provider, you are responsible for applying your clinical judgment regarding the appropriate care and treatment of each patient.

Submit Enrollment Form to the THERA patient support® program ☐

After receiving an Enrollment Form, THERA patient support®:
- Conducts a benefits investigation
- Provides, as per the patient's insurance, instructions on Prior Authorization next steps (**Initial Authorization Criterion**: *EGRIFTA WR*™ will be approved based on the diagnosis of HIV-associated lipodystrophy)

Submit Necessary Clinical Information and Documentation Along with the Prior Authorization Request Form for *EGRIFTA WR*™ ☐

Important clinical information and documentation you may want to consider including:
- Patient's current antiretroviral medications and medical history documenting HIV (B20) and HIV-associated lipodystrophy (E88.14)
- Risk for medical complications due to excess abdominal fat
- Documentation demonstrating that the patient meets the following baseline measurements (clearly indicate if the measurement is in inches or cm):
  - Males: Waist circumference >37.4 inches (95 cm) AND waist-to-hip ratio >0.94
  - Females: Waist circumference >37 inches (94 cm) AND waist-to-hip ratio >0.88

Some plans may require documentation demonstrating:
- Body mass index >20 kg/m^2
- Fasting blood glucose <150 mg/dL (8.33 mmol/L)
- Symptoms associated with lipodystrophy, such as shortness of breath and abdominal pain

If the patient is enrolled in THERA patient support®, the program can provide information on plan-specific requirements and paperwork.

Provide a Description of *EGRIFTA WR*™ Treatment ☐

Accurately complete details about dosage and directions for use:
- Daily subcutaneous injection of a 1.28 mg dose of *EGRIFTA WR*™ (0.16 mL). One reconstituted *EGRIFTA WR*™ vial provides daily doses for 7 consecutive days.

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. For additional Safety Information, please refer to page 2 of this document.

Take the Necessary Steps After Submission ☐

After you have submitted the Prior Authorization request to the insurer:
- Keep copies of all your submitted documentation
- If the payer requests additional documentation or information, provide it as soon as possible

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Respond Appropriately in the Case of a Denial ☐

For patients enrolled in the THERA patient support® program, fax a copy of the denial letter to1-855-836-3069.
THERA patient support® can assist with the appeals process by providing research on appeals requirements for the particular payer.

To access more resources such as the *EGRIFTA WR*™ Letter of Medical Necessity and Letter of Appeal, please scan the QR code to visit THERAPatientSupportUS.com.

Please see next page for Important Safety Information about *EGRIFTA WR*™ (tesamorelin) for injection.

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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