THERA patient support®

EGRIFTA SV® tesamorelin for injection

Prior Authorization Checklist for *EGRIFTA SV®* (tesamorelin for injection)

Your patient's health insurance plan may require **prior authorization (PA)** before approving *EGRIFTA SV®* (2.0 mg/vial). When submitting a PA request for *EGRIFTA SV®*, 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 you submit.

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

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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 SV®* 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 SV®*

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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 (E88.1)
- 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 SV®* Treatment

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Accurately complete details about dosage and directions for use:

- Daily subcutaneous injection of a 1.4 mg dose of *EGRIFTA SV®* (0.35mL), requiring 1 vial of *EGRIFTA SV®* 2 mg

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 refer to page 2 of this document.

Take the Necessary Steps After Submission

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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

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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.

If you need assistance, the following resources are available to use as guides:

- Letter of Medical Necessity
- Letter of Appeal

Please see next page for important risk information about *EGRIFTA SV®* (tesamorelin for injection).

Important Risk Information about *EGRIFTA SV®* (tesamorelin for injection)

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.

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