Louisiana Medicaid
Tesamorelin (Egrifta®; Egrifta SV™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tesamorelin (Egrifta®; Egrifta SV™).

Additional Point-of-Sale edits may apply.

Approval Criteria

- The recipient has a diagnosis of HIV-associated lipodystrophy with excess abdominal fat; **AND**
- The recipient is at least 18 years of age but not older than 65 years of age on the date of the request; **AND**
- Tesamorelin (Egrifta®; Egrifta SV™) is prescribed by, or the request states that this medication is being prescribed in consultation with, an infectious disease specialist or an HIV practitioner; **AND**
- The following is true, and dates/results of testing within the previous 30-day period are **stated on the request:**
    - For men:
        i. A waist circumference ≥95 cm (37.4 inches); **AND**
        ii. A waist-to-hip ratio ≥0.94; **OR**
    - For women:
        i. A negative pregnancy test for females of childbearing potential; **AND**
        ii. A waist circumference ≥94 cm (37.0 inches); **AND**
        iii. A waist-to-hip ratio ≥0.88; **AND**
- The following baseline labs have been performed within the previous 30-day period, and dates/results of testing are **stated on the request**:
    - Triglyceride level; **AND**
    - Hemoglobin A1c; **AND**
    - Insulin-like Growth Factor – 1 (IGF-1); **AND**
- The recipient's most recent BMI is >20 kg/m^2 (date and result of most current BMI calculation is **written on the request**); **AND**
- The dose does not exceed 2mg/day; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient has been compliant on a stable anti-retroviral regimen for at least 8 weeks prior to initiating treatment with tesamorelin [list current anti-retroviral regimen with start date(s)]; **AND**
    - The recipient **DOES NOT HAVE** type 1 diabetes, type 2 diabetes, a history of malignancy, or hypopituitarism; **AND**
    - The recipient **HAS NOT** been treated previously with insulin **OR** oral hypoglycemics **OR** insulin-sensitizing agents; **AND**
    - The female recipient **IS NOT** pregnant and will utilize effective birth control methods while on the requested medication; **AND**

- The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria (**except** baseline body measurements); **AND**
- The prescriber **states on the request** that there is evidence of clear clinical improvement from baseline that is supported by an improvement in waist circumference or results of CT scan. **Must show improvement in waist circumference or visceral adipose tissue by CT scan and/or improvement in triglyceride levels.**

Duration of initial and reauthorization approval: 6 months

References

Egrifta (tesamorelin) [package insert]. Montreal, Quebec, Canada: Theratechnologies Inc.; July 2018. http://egrifta.com/PDF/Prescribing_Info_en.pdf

Egrifta SV™ (tesamorelin) [package insert]. Montreal, Quebec, Canada: Theratechnologies Inc.; July 2019. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022505s012s013lbl.pdf

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