Louisiana Medicaid

~~**Tesamorelin (Egrifta®; Egrifta SV™)**~~ **Growth Factors**

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

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*
~~*Some medications in this therapeutic category may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*~~

Mecasermin (Increlex®)

Approval Criteria

- The recipient is at least 2 years of age, but not older than 18 years of age on the date of the request; **AND**
- The recipient has **ONE** of the following diagnoses **stated on the request**:
  - Growth failure with a diagnosis of severe primary insulin-like growth factor deficiency (PIGFD) as defined by:
    - Height more than three standard deviations below the mean for age; **AND**
    - IGF-1 level more than three standard deviations below the mean for age; **OR**
  - Growth hormone (GH) gene deletion and has developed neutralizing antibodies to GH; **AND**
- Mecasermin is being prescribed by, or the request states that mecasermin is being prescribed in consultation with, an endocrinologist; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - 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**
  - The recipient has open epiphyses and has not reached full adult height; **AND**
  - The recipient does not have any active or suspected malignancy; **AND**
  - The prescriber has educated the patient and/or caregiver on:
    - ~~h~~How to recognize the signs and symptoms of hypoglycemia; **AND**
    - ~~h~~How to recognize the signs and symptoms of serious allergic reactions and the need to seek prompt medical contact should such a reaction occur; **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:

- Recipient continues to meet initial approval criteria; **AND**
- Prescriber **states on the request** that there is evidence of a positive response to therapy as indicated by improvement in signs, symptoms, and/or lab results compared to baseline.

Duration of initial and reauthorization approval: 12 months

Tesamorelin (Egrifta SV™)

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:
    - A waist circumference ≥95 cm (37.4 inches); **AND**
    - A waist-to-hip ratio ≥0.94; **OR**
  - For women:
    - A negative pregnancy test for females of childbearing potential; **AND**
    - A waist circumference ≥94 cm (37.0 inches); **AND**
    - 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.; October 2019. https://www.egriftasv.com/_include/PDF/HCP/Prescribing_Info_en.pdf

Increlex (mecasermin) [package insert]. McPherson, KS: Hospira, Incorporated; January 2019. https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/sites/9/2019/01/21153952/Increlex_Full_Prescribing_Information1.pdf

Revision / Date	**Implementation Date~~Date~~**
Increlex® policy created / August 2019	November 2019~~August 2019~~
Egrifta SV™ ~~P~~policy created / April 2020	August 2020~~April 2020~~
Combined Egrifta SV™ and Increlex® criteria, formatting changes / April 2021	~~April 2021~~July 2021