Louisiana Medicaid
Growth Factors

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for growth factors.

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.*

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**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product - ONE of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **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:
  - How to recognize the signs and symptoms of hypoglycemia; **AND**
  - 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 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**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **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

Vosoritide (Voxzogo™)

This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Approval Criteria

- ~~The recipient is 5 years of age or older on the date of request; **AND**~~
- The recipient has a diagnosis of achondroplasia (ICD-10 code Q77.4); **AND**
- The medication is prescribed by, or the request states that the medication is prescribed in consultation with, an endocrinologist; **AND**
- The prescriber **states on the request** that the recipient has open epiphyses; **AND**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **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**
    - 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 receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

References

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; December 2019. https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/sites/9/2019/01/21153952/Increlex_Full_Prescribing_Information1.pdf

Voxzogo (vosoritide) [package insert]. Novato, CA: BioMarin Pharmaceutical Inc; OctoberNovember 20231. https://voxzogo.com/wp-content/themes/voxzogo/images/prescribing_information.pdf

Revision / Date	Implementation Date
Increlex® policy created / August 2019	November 2019
Egrifta SV™ policy created / April 2020	August 2020
Combined Egrifta SV™ and Increlex® criteria, formatting changes / April 2021	July 2021
Added Voxzogo™, formatting changes, updated references / February 2022	July 2022
Removed age requirement and added accelerated approval statement for Voxzogo™, updated references / November 2023	April 2024