Louisiana Medicaid
Teduglutide (Gattex ®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for teduglutide (Gattex®).

Approval Criteria

- Recipient is 1 year old or older on the date of the request; **AND**
- Recipient has a diagnosis of Short Bowel Syndrome (SBS); **AND**
- Recipients 1 to 16 years of age must:
    - weigh 10 kg or more; **AND**
    - currently be dependent on parenteral support; **AND**
- Recipients 17 years of age and older must have been dependent on parenteral support for at least 12 months [**Document begin date or earliest available date on request**]; **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 teduglutide (Gattex®); **AND**
    - The recipient will not receive teduglutide (Gattex®) in combination with any medication that is contraindicated or not recommended per FDA labeling; **AND**
    - Optimization of adjunctive medications and dietary modifications have been completed prior to requesting teduglutide (Gattex®); **AND**
    - Recipients have completed the following testing 6 months or less prior to the date of the request:
        - baseline laboratory assessment (bilirubin, alkaline phosphatase, lipase and amylase); **AND**
        - fecal occult blood testing with follow up as recommended in the prescribing information (for recipients 1 to 16 years); **OR**
        - colonoscopy with removal of polyps (for recipients 17 years and older).

Reauthorization Criteria

- Recipient is 1 year old or older on the date of the request; **AND**
- Recipient has a diagnosis of Short Bowel Syndrome (SBS); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - Recipient still requires parenteral support, **HOWEVER,** a **reduction in volume** of parenteral support since initiation of treatment with teduglutide (Gattex®) when compared to baseline has been achieved; **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 teduglutide (Gattex®), and will not receive teduglutide (Gattex®) in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval: 12 months

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

Reference

Gattex® (Teduglutide) [package insert]. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; June 2019. Retrieved from https://www.shirecontent.com/PI/PDFS/Gattex_USA_ENG.pdf

Revision	Date
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