Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PHAR.114	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Teduglutide (Gattex)	

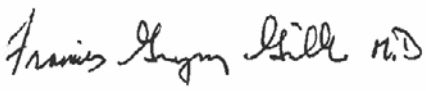
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2020 annual review: revised age requirement from 18 years to 1 year to align with updated prescribing information; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Teduglutide (Gattex)

Reference Number: PA.CP.PHAR.114
Effective Date: 01/18
Last Review Date: 01/2020

Coding Implications
Revision Log

Description
Teduglutide (Gattex®) is a glucagon-like peptide-2 analog.

FDA Approved Indication(s)
Gattex is indicated for treatment of adult and pediatric patients 1 year of age and older with short bowel syndrome (SBS) who are dependent on parenteral support.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Gattex is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Short Bowel Syndrome (must meet all):

1. Diagnosis of short bowel syndrome;
2. Prescribed by or in consultation with a gastroenterologist;
3. Age ≥ 1 year;
4. Dependent on parenteral nutrition or other intravenous support for ≥ 12 months;
5. Dose does not exceed 0.05 mg/kg per day.

Approval duration: 12 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Short Bowel Syndrome (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Requirement for parenteral nutrition or other intravenous support has decreased since initiation of Gattex therapy;
3. If request is for a dose increase, new dose does not exceed 0.05 mg/kg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
SBS: short bowel syndrome

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
somatropin (e.g., Norditropin)	Refer to prescribing information (*dosing is individualized depending on nature and severity of disease, formulation, and patient response*)	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
SBS	0.05 mg/kg SC QD	0.05 mg/kg/day

V. Product Availability

Single-use vial: 5 mg

VI. References

1. Gattex Prescribing Information. Lexington, MA: Shire-NPS Pharmaceuticals, Inc.; June 2019. Available at http://www.gattex.com. Accessed November 6, 2019.
2. Parrish CR, DiBaise JK. Managing the adult patient with short bowel syndrome. Gastroenterology & Hepatology. October 2017; 13(10): 600-608.
3. Seidner DL, Schwartz LK, Winkler MF, et al. Increased intestinal absorption in the era of teduglutide and its impact on management strategies in patients with short bowel syndrome – associated intestinal failure. JPEN. 2013; 37: 201-2011.

Reviews, Revisions, and Approvals	Date	Approval Date
Age added. Preferencing for Zorptive added. The following criteria are removed given the 12-month PN requirement: colonosopy; PN ≥ 3 times per week; use of antimotility and antisecretory agents. “Consecutive” removed from the 12-month PN requirement. Initial duration is increased from 6 to	02/18	

Reviews, Revisions, and Approvals	Date	Approval Date
12 months to allow more time for therapeutic response; continued therapy duration is increased from 6 to 12 months. References reviewed and updated.		
1Q 2019 annual review; references reviewed and updated.	01/19	
1Q 2020 annual review: revised age requirement from 18 years to 1 year to align with updated prescribing information; references reviewed and updated.	01/20	