

Clinical Policy Title:	teduglutide
Policy Number:	RxA.150
Drug(s) Applied:	Gattex®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All line of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Member has a diagnosis of SBS;
2. Member is dependent on parenteral nutrition or other intravenous (IV) support for ≥ 12 months.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Parrish CR, DiBaise JK. Managing the adult patient with short bowel syndrome. *Gastroenterology & Hepatology*. October 2017; 13(10): 600-608. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5718176/>. Accessed August 28, 2024.
2. Schwartz LK, O'Keefe SJD, Fujioka K, et al. Long-term teduglutide for the treatment of patients with intestinal failure associated with short bowel syndrome. *Clin Transl Gastroenterol*. 2016; 7: e142. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4817413/>. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Continuation therapy criteria II.A.1. was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance". 2. Initial therapy and continued therapy approval duration for "commercial" was updated. 3. References were updated. 	06/15/2020	09/14/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Clinical Policy title was updated. 2. Initial criteria for approval and duration updated. 3. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 4. References were reviewed and updated. 	03/03/2021	06/10/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were reviewed and updated. 	01/11/2022	04/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.5: Updated to remove, <ol style="list-style-type: none"> a. For members 18 years of age or older: Use of parenteral nutrition/IV fluids occurs at least three (3) times a week; or b. For members under 18 years of age: Use of parenteral nutrition/IV fluids account for at least 30% of caloric and/or fluid/electrolyte needs. 2. Initial Approval Criteria I.A.5: Updated to remove Failure of a 4-week trial of somatropin (e.g., Zorbtive®) unless contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria I.A.4: Updated to add Weight ≥ 10 kg. 4. References were reviewed and updated. 	04/12/2023	04/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Removed weight restriction. 5. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 6. Removed reauthorization criteria for decreased requirement of parenteral nutrition or other IV support. 7. Updated approval duration verbiage. 8. References were reviewed and updated. 	08/28/2024	09/13/2024