

Pharmacy Policy

Gattex®

Policy Number: 9.802

Version Number: 2.0

Version Effective Date: 3/1/2022

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Gattex (teduglutide)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	<ol style="list-style-type: none"> 1. A diagnosis of short bowel syndrome; AND 2. Short bowel syndrome management has been dependent on parenteral nutrition support for at least 12 months prior to initiation of therapy with Gattex; AND 3. Dose does not exceed 0.05 mg/kg per day

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Age Restrictions	Member is 1 year of age or older
Prescriber Restriction	Prescribed by or in consultation with a gastroenterologist or endocrinologist
Coverage Duration	<u>Initial:</u> 6 months <u>Reauthorization:</u> 12 months
Other criteria	Reauthorization <ol style="list-style-type: none"> 1. Diagnosis of short bowel syndrome; AND 2. Medical records have been provided that show that there has been a reduction in the need for parenteral nutrition support by at least 20% as a result of Gattex treatment; AND 3. There have not been any serious treatment-related adverse events; AND 4. Dose does not exceed 0.05 mg/kg per day

Applicable Coding:

None

Clinical Background Information and References

1. Gattex[®] Prescribing Information. NPS Pharmaceuticals. Bedminster, NJ 07921. February, 2021
2. DiBaise JK. Management of the Short Bowel Syndrome in Adults. UpToDate. Last updated March 20, 2021. Available: www.uptodate.com. Accessed October 2021.
3. Nightingale J and Woodward JM. Guidelines for Management of patients with a Short Bowel. Gut. Aug 2006; 55(Supple 4):iv1-iv12.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	P&T Annual Review, 9.046 Gattex Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	P&T Annual Review. Removed colonoscopy requirement; added max dosing criterion; updated coverage duration to be 12 months for reauthorization; added diagnosis and dosing criteria to reauthorization.	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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