



Gattex Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
01-01-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Gattex	teduglutide (rdna) for inj kit	5 MG	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Gattex	teduglutide (rdna) for inj kit	5 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of short bowel syndrome (SBS) and ALL of the following: <ol style="list-style-type: none"> 1. The patient has less than 200 cm of functional small intestine [chart notes required] AND 2. ONE of the following:

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	<p>A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>B. BOTH of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR <p>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR</p> <p>D. The patient has tried and had an inadequate response to maximal use of TWO anti-diarrheal agents (e.g., loperamide AND diphenoxylate) used concomitantly with oral rehydration solution [chart notes required] OR</p> <p>E. Maximal use of TWO anti-diarrheal agents (e.g., loperamide AND diphenoxylate) used concomitantly with oral rehydration solution was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>F. The patient has an intolerance or hypersensitivity to maximal use of TWO anti-diarrheal agents (e.g., loperamide AND diphenoxylate) used concomitantly with oral rehydration solution [chart notes required] OR</p> <p>G. The patient has an FDA labeled contraindication to ALL anti-diarrheal agents (e.g., loperamide AND diphenoxylate) used concomitantly with oral rehydration solution [chart notes required] OR</p> <p>H. Maximal use of TWO anti-diarrheal agents (e.g., loperamide AND diphenoxylate) used concomitantly with oral rehydration solution is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>I. Maximal use of TWO anti-diarrheal agents (e.g., loperamide AND diphenoxylate) used concomitantly with oral rehydration solution is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>J. The patient has tried another drug in the same pharmacologic class or with the same mechanism of action as TWO anti-diarrheal agents (e.g., loperamide AND diphenoxylate) used concomitantly with oral rehydration solution and that drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>3. The patient is currently receiving parenteral nutrition/intravenous fluids (PN/IV) at least 3 days per week [medical records including daily volume of parenteral nutrition and/or intravenous fluids] AND</p> <p>4. ONE of the following:</p>

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	<p>A. The patient is a pediatric patient at least 1 year of age AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. A fecal occult blood test has been performed within 6 months prior to initiating treatment with the requested agent AND 2. ONE of the following: <ol style="list-style-type: none"> A. There was no new or unexplained blood in the stool OR B. There was new or unexplained blood in the stool AND a colonoscopy/sigmoidoscopy and upper GI endoscopy was performed OR <p>B. The patient is an adult AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient has had a colonoscopy and upper GI endoscopy within 6 months prior to initiating treatment with the requested agent [medical records including date of last colonoscopy] AND 2. If polyps were present at this colonoscopy and upper GI endoscopy, the polyps were removed OR <p>B. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <ol style="list-style-type: none"> 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent AND 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months ALL other plans: 6 months</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR

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	<p data-bbox="488 180 1417 443"> 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] </p> <p data-bbox="232 478 1417 537">Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p data-bbox="232 573 1417 661">Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p data-bbox="232 697 500 730">Length of Approval:</p> <p data-bbox="232 766 570 825">BCBSOK: 36 months ALL other plans: 12 months</p> <p data-bbox="232 861 1076 894">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p data-bbox="232 989 500 1022">Renewal Evaluation</p> <p data-bbox="232 1058 1081 1092">Target Agent(s) will be approved when ALL of the following are met:</p> <ol data-bbox="280 1127 1417 1413" style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] AND 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 3. The patient has had clinical benefit with the requested agent AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent AND 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication <p data-bbox="232 1449 500 1482">Length of Approval:</p> <p data-bbox="232 1518 570 1577">BCBSOK: 36 months ALL other plans: 12 months</p>