

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Gattex (teduglutide)

This criteria was recommended for review by the Texas Medicaid Vendor Drug Program to ensure appropriate and safe utilization.

Clinical Information Included in this Document

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

Initial publication and presentation to the DUR Board



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Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
GATTEX 5 MG 30-VIAL KIT	33927



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Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 1 year of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of **short bowel syndrome** in the last 730 days?
 Yes (Go to #3)
 No (Deny)
3. Is the client currently dependent on **parenteral support**?
 Yes (Go to #4)
 No (Deny)
4. Is this a renewal request?
 Yes (Go to #12)
 No (Go to #5)
5. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #6)
 No (Go to #7)
6. Has the client had a **colonoscopy** in the last 180 days?
 Yes (Go to #8)
 No (Deny)
7. Has the client had **fecal occult blood testing** in the last 180 days?
 Yes (Go to #8)
 No (Deny)
8. Does the client have a diagnosis of **intestinal or stomal obstruction** in the last 180 days?
 Yes (Deny)
 No (Go to #9)
9. Does the client have a diagnosis of **moderate to severe renal impairment or end-stage renal disease** in the last 365 days?
 Yes (Go to #11)
 No (Go to #10)
10. Is the requested dose greater than ($>$) 0.05 mg/kg daily? [Manual]
 Yes (Deny)
 No (Approve – 180 days)

11. Is the requested dose greater than (>) 0.025 mg/kg daily? [Manual]

Yes (Deny)

No (Approve – 180 days)

12. Does the client continue to receive clinical benefit from treatment with Gattex?

[Manual]

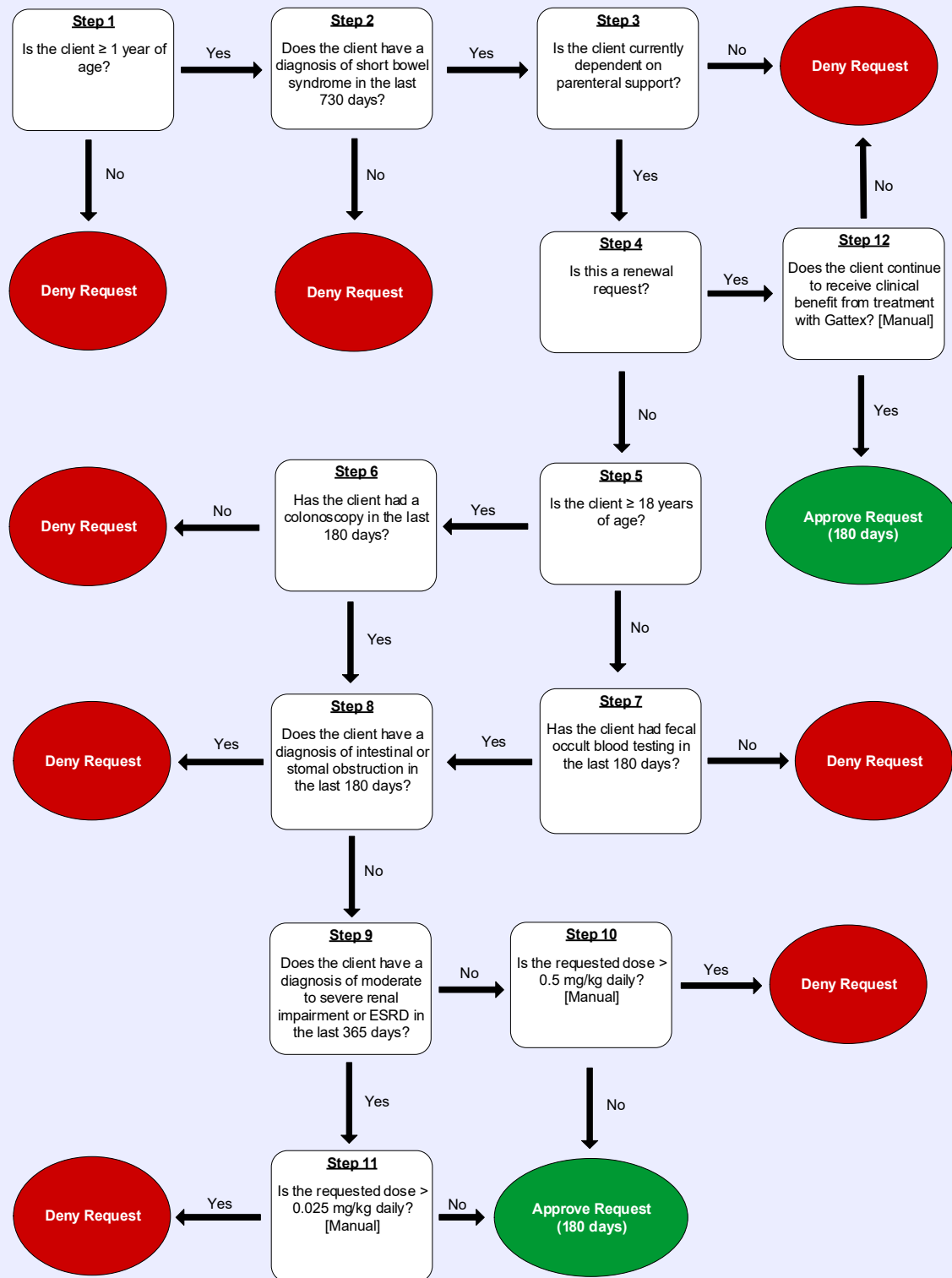
Yes (Approve – 180 days)

No (Deny)



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Clinical Criteria Logic Diagram





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Clinical Criteria Supporting Tables

Step 2 (diagnosis of short bowel syndrome)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
K912	POSTSURGICAL MALABSORPTION, NOT ELSEWHERE CLASSIFIED

Step 3 (parenteral support)	
HCPCS Code	Description
B4164	PARENTERAL NUTRITION SOLUTION: CARBOHYDRATES (DEXTROSE), 50% OR LESS (500 ML = 1 UNIT) - HOMEMIX
B4168	PARENTERAL NUTRITION SOLUTION; AMINO ACID, 3.5%, (500 ML = 1 UNIT) - HOMEMIX
B4172	PARENTERAL NUTRITION SOLUTION; AMINO ACID, 5.5% THROUGH 7%, (500 ML = 1 UNIT) - HOMEMIX
B4176	PARENTERAL NUTRITION SOLUTION; AMINO ACID, 7% THROUGH 8.5%, (500 ML = 1 UNIT) - HOMEMIX
B4178	PARENTERAL NUTRITION SOLUTION: AMINO ACID, GREATER THAN 8.5% (500 ML = 1 UNIT) - HOMEMIX
B4180	PARENTERAL NUTRITION SOLUTION; CARBOHYDRATES (DEXTROSE), GREATER THAN 50% (500 ML=1 UNIT) - HOMEMIX
B4185	PARENTERAL NUTRITION SOLUTION, NOT OTHERWISE SPECIFIED, 10 GRAMS LIPIDS
B4187	OMEGAVEN, 10 GRAMS LIPIDS
B4189	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 10 TO 51 GRAMS OF PROTEIN - PREMIX
B4193	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 52 TO 73 GRAMS OF PROTEIN - PREMIX
B4197	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 74 TO 100 GRAMS OF PROTEIN - PREMIX
B4199	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, OVER 100 GRAMS OF PROTEIN - PREMIX

Step 3 (parenteral support)	
HCPCS Code	Description
B4216	PARENTERAL NUTRITION; ADDITIVES (VITAMINS, TRACE ELEMENTS, HEPARIN, ELECTROLYTES) HOMEMIX PER DAY
B4220	PARENTERAL NUTRITION SUPPLY KIT; PREMIX, PER DAY
B4222	PARENTERAL NUTRITION SUPPLY KIT; HOME MIX, PER DAY
B4224	PARENTERAL NUTRITION ADMINISTRATION KIT, PER DAY
B5000	PARENTERAL NUTRITION SOLUTION COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, RENAL-AMIROSYN RF, NEPHRAMINE, RENAMINE-PREMIX
B5100	PARENTERAL NUTRITION SOLUTION COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, HEPATIC, HEPATAMINE-PREMIX
B5200	PARENTERAL NUTRITION SOLUTION COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, STRESS-BRANCH CHAIN AMINO ACIDS-FREAMINE-HBC-PREMIX

Step 6 (history of colonoscopy)	
Required claims: 1	
Look back timeframe: 180 days	
ICD-10/CPT Code	Description
44388	COLONOSCOPY THROUGH STOMA; DIAGNOSTIC, INCLUDING COLLECTION OF SPECIMEN(S) BY BRUSHING OR WASHING, WHEN PERFORMED (SEPARATE PROCEDURE)
44389	COLONOSCOPY THROUGH STOMA; WITH BIOPSY, SINGLE OR MULTIPLE
44390	COLONOSCOPY THROUGH STOMA; WITH REMOVAL OF FOREIGN BODY(S)
44391	COLONOSCOPY THROUGH STOMA; WITH CONTROL OF BLEEDING, ANY METHOD
44392	COLONOSCOPY THROUGH STOMA; WITH REMOVAL OF TUMOR(S), POLYP(S), OR OTHER LESION(S) BY HOT BIOPSY FORCEPS
44394	COLONOSCOPY THROUGH STOMA; WITH REMOVAL OF TUMOR(S), POLYP(S), OR OTHER LESION(S) BY SNARE TECHNIQUE
44401	COLONOSCOPY THROUGH STOMA; WITH ABLATION OF TUMOR(S), POLYP(S), OR OTHER LESION(S) (INCLUDES PRE-AND POST-DILATION AND GUIDE WIRE PASSAGE, WHEN PERFORMED)
44402	COLONOSCOPY THROUGH STOMA; WITH ENDOSCOPIC STENT PLACEMENT (INCLUDING PRE- AND POST-DILATION AND GUIDE WIRE PASSAGE, WHEN PERFORMED)
44404	COLONOSCOPY THROUGH STOMA; WITH DIRECTED SUBMUCOSAL INJECTION(S), ANY SUBSTANCE

Step 6 (history of colonoscopy)	
Required claims: 1	
Look back timeframe: 180 days	
ICD-10/CPT Code	Description
44405	COLONOSCOPY THROUGH STOMA; WITH TRANSENDOSCOPIC BALLOON DILATION
44406	COLONOSCOPY THROUGH STOMA; WITH ENDOSCOPIC ULTRASOUND EXAMINATION, LIMITED TO THE SIGMOID, DESCENDING, TRANSVERSE, OR ASCENDING COLON AND CECUM AND ADJACENT STRUCTURES
44407	COLONOSCOPY THROUGH STOMA; WITH TRANSENDOSCOPIC ULTRASOUND GUIDED INTRAMURAL OR TRANSMURAL FINE NEEDLE ASPIRATION/BIOPSY(S), INCLUDES ENDOSCOPIC ULTRASOUND EXAMINATION LIMITED TO THE SIGMOID, DESCENDING, TRANSVERSE, OR ASCENDING COLON AND CECUM AND ADJACENT STRUCTURES
45378	COLONOSCOPY, FLEXIBLE; DIAGNOSTIC, INCLUDING COLLECTION OF SPECIMEN(S) BY BRUSHING OR WASHING, WHEN PERFORMED (SEPARATE PROCEDURE)
45379	COLONOSCOPY, FLEXIBLE; WITH REMOVAL OF FOREIGN BODY(S)
45380	COLONOSCOPY, FLEXIBLE; WITH BIOPSY, SINGLE OR MULTIPLE
45381	COLONOSCOPY, FLEXIBLE; WITH DIRECTED SUBMUCOSAL INJECTION(S), ANY SUBSTANCE
45382	COLONOSCOPY, FLEXIBLE; WITH CONTROL OF BLEEDING, ANY METHOD
45384	COLONOSCOPY, FLEXIBLE; WITH REMOVAL OF TUMOR(S), POLYP(S), OR OTHER LESION(S) BY HOT BIOPSY FORCEPS
45385	COLONOSCOPY, FLEXIBLE; WITH REMOVAL OF TUMOR(S), POLYP(S), OR OTHER LESION(S) BY SNARE TECHNIQUE
45386	COLONOSCOPY, FLEXIBLE; WITH TRANSENDOSCOPIC BALLOON DILATION
45388	COLONOSCOPY, FLEXIBLE; WITH ABLATION OF TUMOR(S), POLYP(S), OR OTHER LESION(S) (INCLUDES PRE- AND POST-DILATION AND GUIDE WIRE PASSAGE, WHEN PERFORMED)
45389	COLONOSCOPY, FLEXIBLE; WITH ENDOSCOPIC STENT PLACEMENT (INCLUDES PRE- AND POST-DILATION AND GUIDE WIRE PASSAGE, WHEN PERFORMED)
45391	COLONOSCOPY, FLEXIBLE; WITH ENDOSCOPIC ULTRASOUND EXAMINATION LIMITED TO THE RECTUM, SIGMOID, DESCENDING, TRANSVERSE, OR ASCENDING COLON AND CECUM, AND ADJACENT STRUCTURES
45392	COLONOSCOPY, FLEXIBLE; WITH TRANSENDOSCOPIC ULTRASOUND GUIDED INTRAMURAL OR TRANSMURAL FINE NEEDLE ASPIRATION/BIOPSY(S), INCLUDES ENDOSCOPIC ULTRASOUND EXAMINATION LIMITED TO THE RECTUM, SIGMOID, DESCENDING, TRANSVERSE, OR ASCENDING COLON AND CECUM, AND ADJACENT STRUCTURES
45393	COLONOSCOPY, FLEXIBLE; WITH DECOMPRESSION (FOR PATHOLOGIC DISTENTION) (EG, VOLVULUS, MEGACOLON),

Step 6 (history of colonoscopy)	
Required claims: 1	
Look back timeframe: 180 days	
ICD-10/CPT Code	Description
	INCLUDING PLACEMENT OF DECOMPRESSION TUBE, WHEN PERFORMED
Z1211	ENCOUNTER FOR SCREENING FOR MALIGNANT NEOPLASM OF COLON

Step 7 (history of fecal occult blood testing)	
Required quantity: 1	
Look back timeframe: 180 days	
CPT/HCPCS Code	Description
82270	COLORECTAL CANCER SCREENING; FECAL-OCCULT BLOOD TEST
G0328	COLORECTAL CANCER SCREENING; FECAL-OCCULT BLOOD TEST

Step 8 (diagnosis of intestinal or stomal obstruction)	
Required diagnosis: 1	
Look back timeframe: 180 days	
ICD-10 Code	Description
K5650	INTESTINAL ADHESIONS [BANDS], UNSPECIFIED AS TO PARTIAL VERSUS COMPLETE OBSTRUCTION
K5651	INTESTINAL ADHESIONS [BANDS], WITH PARTIAL OBSTRUCTION
K5652	INTESTINAL ADHESIONS [BANDS] WITH COMPLETE OBSTRUCTION
K56600	PARTIAL INTESTINAL OBSTRUCTION, UNSPECIFIED AS TO CAUSE
K56601	COMPLETE INTESTINAL OBSTRUCTION, UNSPECIFIED AS TO CAUSE
K56609	UNSPECIFIED INTESTINAL OBSTRUCTION UNSPECIFIED AS TO PARTIAL VERSUS COMPLETE OBSTRUCTION
K56690	OTHER PARTIAL INTESTINAL OBSTRUCTION
K56691	OTHER COMPLETE INTESTINAL OBSTRUCTION
K56699	OTHER INTESTINAL OBSTRUCTION UNSPECIFIED AS TO PARTIAL VERSUS COMPLETE OBSTRUCTION
K9409	OTHER COMPLICATIONS OF COLOSTOMY

Step 9 (diagnosis of moderate to severe renal impairment or ESRD)	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
N1830	CHRONIC KIDNEY DISEASE, STAGE 3 UNSPECIFIED (eGFR < 60 mL/min/1.73m ² to ≥ 30 mL/min/1.73m ²)

Step 9 (diagnosis of moderate to severe renal impairment or ESRD)	
Required diagnosis: 1	
Look back timeframe: 365 days	
N1831	CHRONIC KIDNEY DISEASE, STAGE 3A (eGFR < 60 mL/min/1.73m ² to ≥ 45 mL/min/1.73m ²)
N1832	CHRONIC KIDNEY DISEASE, STAGE 3B (eGFR < 45 mL/min/1.73m ² to ≥ 30 mL/min/1.73m ²)
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE) (eGFR < 30 mL/min/1.73m ² to ≥ 15 mL/min/1.73m ²)
N185	CHRONIC KIDNEY DISEASE, STAGE 5 (eGFR < 15 mL/min/1.73m ²)
N186	END STAGE RENAL DISEASE



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Clinical Criteria References

1. 2023 ICD-10-CM Diagnosis Codes. 2023. Available at www.icd10data.com. Accessed on April 28, 2023.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2023. Available at www.clinicalpharmacology.com. Accessed on April 28, 2023.
3. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on April 28, 2023.
4. Gattex Prescribing Information. Lexington, MA. Takeda Pharmaceuticals USA, Inc. October 2022.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
04/28/2023	<ul style="list-style-type: none">• Initial publication and presentation to the DUR Board