

Texas Prior Authorization Program
Clinical Edit Criteria

Drug/Drug Class

Amitiza (Lubiprostone)

Clinical Edit Information Included in this Document

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

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

Revision Notes

Revised step 4 of clinical edit criteria logic to include diagnosis of chronic idiopathic constipation or opioid-induced constipation with chronic, non-cancer pain



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Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
AMITIZA (LUBIPROSTONE) 8 MCG	99658
AMITIZA (LUBIPROSTONE) 24MCG CAPSULES	26473



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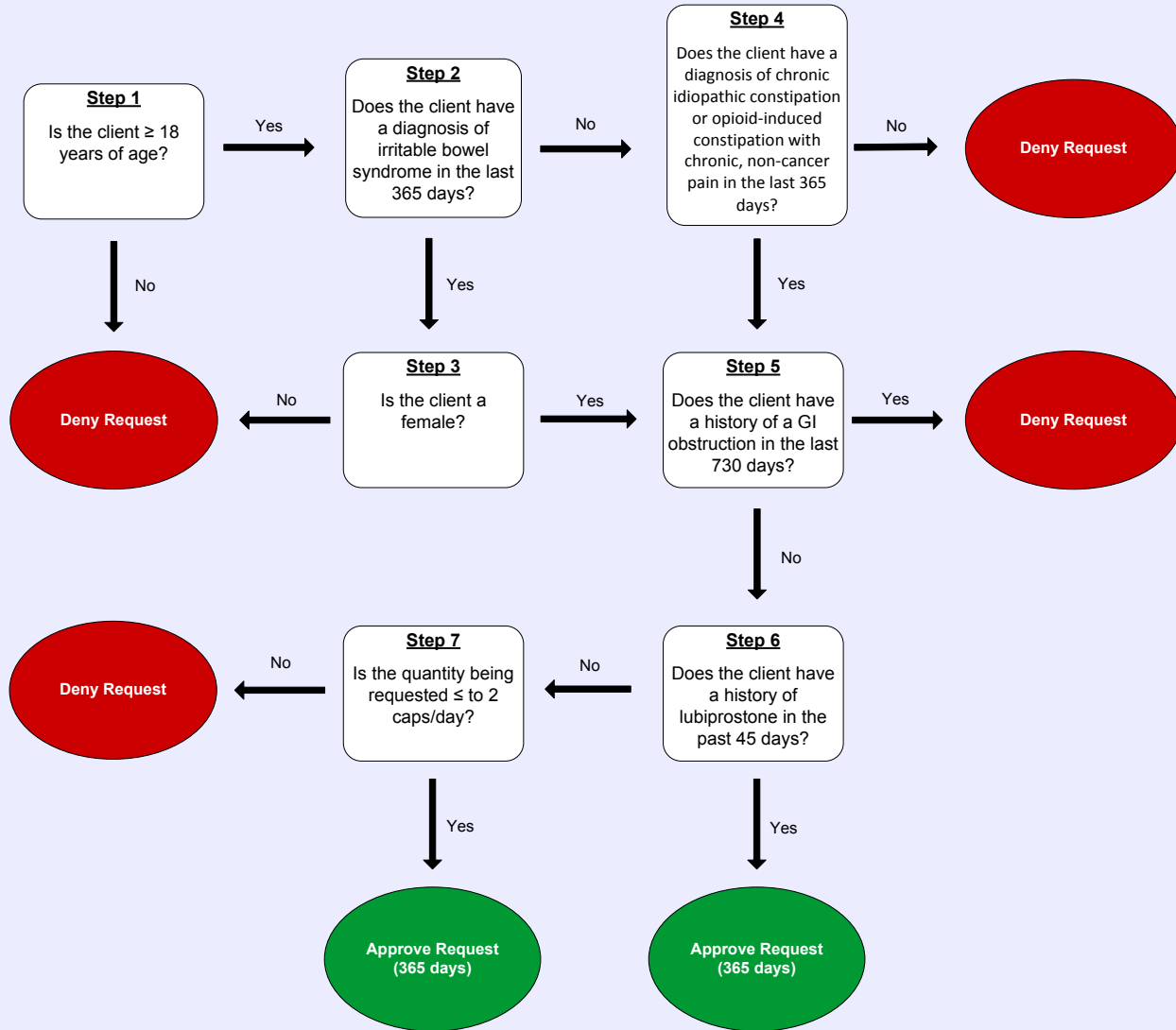
Clinical Edit Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of irritable bowel syndrome in the last 365 days?
 Yes (Go to #3)
 No (Go to #4)
3. Is the client a female?
 Yes (Go to #5)
 No (Deny)
4. Does the client have a diagnosis of chronic idiopathic constipation or opioid-induced constipation with chronic, non-cancer pain in the last 365 days?
 Yes (Go to #5)
 No (Deny)
5. Does the client have a history of a GI obstruction in the last 730 days?
 Yes (Deny)
 No (Go to #6)
6. Does the client have a history of lubiprostone in the past 45 days?
 Yes (Approve – 365 days)
 No (Go to #7)
7. Is the quantity being requested less than or equal to (\leq) 2 caps/day?
 Yes (Approve – 365 days)
 No (Deny)



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Clinical Edit Criteria Logic Diagram





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Clinical Edit Criteria Supporting Tables

Step 2 (diagnosis of irritable bowel syndrome) Required quantity: 1 Look back timeframe: 365 days	
ICD-9 Code	Description
5641	IRRITABLE BOWEL SYNDROME

Step 4 (diagnosis of constipation) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-9 Code	Description
5640	CONSTIPATION
56400	CONSTIPATION, UNSPECIFIED
56401	SLOW TRANSIT CONSTIPATION
56402	OUTLET DYSFUNCTION CONSTIPATION

Step 5 (history of GI obstruction) Required quantity: 1 Look back timeframe: 730 days	
ICD-9 Code	Description
5600	INTUSSUSCEPTION
5601	PARALYTIC ILEUS
5602	VOLVULUS OF INTESTINE
56031	GALLSTONE ILEUS
56081	INTESTINAL ADHES W OBSTR
56089	INTESTINAL OBSTRUCT NEC
5609	INTESTINAL OBSTRUCT NOS

Step 6 (history of lubiprostone) Required quantity: 1 Look back timeframe: 45 days	
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Clinical Edit Criteria References

1. Amitiza™ [package insert]. Deerfield, IL: Takeda Pharmaceuticals North America. Available at <http://www.amitiza.com/>. Accessed on July 7, 2011.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc., updated January 2011. Available at http://www.clinicalpharmacology.com/?epm=2_1.
3. 2011 ICD-9-CM Diagnosis Codes, Volume 1, 2011. Available at <http://www.icd9data.com/>. Accessed on August 14, 2011.

Publication History

The Publication History records the publication iterations and revisions to this document.

Publication Date	Notes
04/12/2012	Initial publication and posting to website
05/24/2013	Revised step 4 to include diagnosis of chronic idiopathic constipation or opioid-induced constipation with chronic, non-cancer pain