



**PHARMACY MEDICAL POLICY**

**Policy #: 093**

**Original policy date: 9/1/09**

**Page: 1 of 3**

**Title**

**Lubiprostone (Amitiza®)**

**Note:** All requests for **outpatient retail pharmacy** for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the **Prior Authorization Form** on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients at (800)366-7778. Patients must have pharmacy benefits under their subscriber certificates.

For Medicare Advantage members, please refer to Medical Policy #023.

Please refer to the chart below for the formulary status of the medications affected by this policy.

Drug	Formulary Information	
	Standard	Blue Value Rx
	Formulary Status	Formulary Status
Amitiza®	PA Required	PA Required

**When services are covered for Commercial products (excluding Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx plans; see below for coverage for these products)**

We cover Amitiza® (lubiprostone) when **one** of the following criteria is met<sup>1</sup>:

- A diagnosis of Irritable Bowel Syndrome (IBS) with constipation (ICD-9-CM diagnosis codes: 564.1)

**OR**

- A diagnosis of chronic constipation (ICD-9-CM diagnosis codes: 564.0)

**AND**

- The member has had previous treatment failure with two or more of the following medications:
  - Polyethylene Glycol 3350 (Miralax®, Glycolax®)
  - Lactulose
  - Sorbitol
  - Bulking agents (i.e. Psyllium, methylcellulose)
  - Docusate sodium
  - Laxatives (i.e. Magnesium citrate, mineral oil, senna, bisacodyl)

**When services are not covered for Commercial Products (excluding Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx products)**

We do not cover Amitiza® (lubiprostone) when the above criteria are not met.

**When services are covered for Medicare HMO Blue, Medicare PPO Blue, and Blue Medicare PFFS PlusRx products.**

For Medicare Advantage members, please refer to Medical Policy #023.

### **Individual consideration**

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature, such as a history of treatment failure or intolerance. Physicians may send relevant clinical information for consideration for individual patients who do not meet the above criteria to:

Blue Cross Blue Shield of Massachusetts  
Clinical Pharmacy Operations  
25 Technology Place  
Hingham, MA 02043  
Tel: (800) 366-7778  
Fax: (800) 583-6289

### **Managed care, PPO and Indemnity guidelines**

Prior Authorization is required for all plans as these drugs are processed as a Pharmacy benefit.

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients:  
Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for prior authorization.

### **Coding information**

Physician billing is not applicable as these medications are billed through the pharmacy benefit.

### **Policy update history**

New Policy, effective 09/01/09.

### **Footnotes**

<sup>1</sup>Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 11/18/08 and 5/12/09.

### **References**

1. Amitiza<sup>®</sup> [package insert]. Deerfield, IL: Takeda Pharmaceuticals America; 2008.

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

©2009 Blue Cross and Blue Shield of Massachusetts, Inc. All rights reserved. Blue Cross and Blue Shield of Massachusetts, Inc. is an Independent Licensee of the Blue Cross and Blue Shield Association.

**Request for Outpatient Retail Pharmacy Prior Authorization**  
**Phone Authorization (800)366-7778**  
**Fax to: Clinical Pharmacy Program (800) 583-6289**

We plan to respond to your request within two business days of our receipt. To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.

We cannot process requests unless they contain <b>all</b> of the information requested below:	
<b>Patient Information (REQUIRED)</b>	
Name	
BCBSMA ID number	
Is the patient a BCBSMA employee? If yes, please fax request to: <b>(617) 246-4013</b>	Yes                  No
Date of Birth	
Patient's Diagnosis or ICD-9-CM code	
<b>Physician Information (REQUIRED)</b>	
Name	
Medical Specialty	
BCBSMA Provider number/NPI number	
Telephone Number	
Fax Number	
Contact Name (if different from physician)	
Please select <b>one</b> of the three following sections to complete, depending on the nature of your request for the above-named patient.	
<b>Formulary Exception Request</b>	
Name of non-covered drug you want to prescribe	
Reason for Individual Consideration Request (please check one): <input type="checkbox"/> Treatment failure with the following covered drugs in class <input type="checkbox"/> Documented adverse reaction to the following covered drugs <input type="checkbox"/> Other clinical reason (please specify) _____	
<b>Quality Care Dosing Override Request</b>	
Drug name, strength and quantity requested:	
Clinical reason for override (please specify)	
<b>Outpatient Retail Pharmacy Prior Authorization Request</b>	
Drug name:	
Start/End date (must be one year or less):	
Associated Co-morbid diagnosis:	
For Epogen®/Procrit® only:	GFR:
	Is patient certified ESRD with Medicare?    Yes    No
MD Signature:	Date: