

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** Constipation and IBS Medications Policy

**Drug(s):** AMITIZA (lubiprostone), LOTRONEX (alosetron)

**Covered Uses:** All FDA-approved indications not otherwise excluded from Part D. All criteria in "other criteria" section must be met for coverage.

Rome II Criteria for the Diagnosis of Irritable Bowel Syndrome:

- Symptoms for at least 12 weeks, which need not be consecutive, in the preceding 12 months **AND**
- Symptoms of abdominal discomfort or pain that has 2 of 3 features:
  - a) relieved with defecation
  - b) and/or associated with a change in frequency of stool
  - c) and/or associated with a change in consistency of stool

Symptoms that cumulatively support the diagnosis of IBS:

- a) altered stool frequency (greater than 3 bowel movements per day for diarrhea-predominant IBS, or less than 3 movements per week for constipation-predominant IBS)
- b) altered stool form (lumpy/hard or loose/watery stool)
- c) altered stool passage (straining, urgency, or feeling of incomplete evacuation)
- d) passage of mucus
- e) bloating or feeling of abdominal distention

**Required Medical Information:** Chart notes identifying duration of diagnosis, number of complete spontaneous BM (CSBM) per week, stool consistency, previous treatments tried. Medical history

**Age Restrictions:** Amitiza: must be between 18 year and 65 years. Lotronex: Restricted to 18 years of age or older

**Prescriber Restrictions:** Restricted to GI specialists. Lotronex: Ordering provider must be enrolled in the GSK Prescribing Program

**Other Criteria:**

**Amitiza** (lubiprostone) chronic idiopathic constipation criteria:

- A. documented history of chronic idiopathic constipation. Chronic constipation is defined as:
  - 1. constipation lasting for longer than 6 months AND
  - 2. less than 3 complete spontaneous bowel movements (CSBM) per week. The CSBM involved straining, incomplete evacuation and/or hard stools with at least 25% of BMs;
  - 3. not having any form of IBS (diarrhea-predominant, constipation-predominant or mixed-type IBS) or loose stools at any time.
  - 4. all external sources of constipation have been eliminated.

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B. failure to respond or intolerance to an adequate trial (duration of at least 1 month) of the following therapies:

1. dietary modification – increased dietary fiber (25 g/day).
2. fiber supplementation – typical Psyllium products provide 3-4 g per dose (e.g. Metamucil, Perdiem Fiber therapy).
3. laxative use (lactulose, polyethylene glycol, etc.).

Initial prior authorization is limited to 4 weeks of therapy.

Continued coverage will be dependent upon documentation to support clinical response and lack of adverse effects to therapy.

Maximum allowable duration of therapy is 12 months.

**Lotronex®** (alosetron) diarrhea-predominant IBS criteria:

A. female

B. severe diarrhea-predominant IBS (meets Rome II criteria for diagnosis of diarrhea-predominant IBS) with chronic IBS symptoms (diarrhea) lasting for at least 6 months. Severe diarrhea-predominant IBS includes diarrhea and one or more of the following:

1. frequent and severe abdominal pain/discomfort
2. frequent bowel urgency or fecal incontinence
3. disability or restriction of daily activities due to IBS

C. Failure to respond to conventional therapy (at least a one month trial) of an agent in 3 or more of the following categories during a period in which the Rome criteria above is met:

1. antidiarrheal (loperamide recommended)
2. bile acid sequestrant/bulking agent
3. antispasmodic
4. combination products of the above agents

Initial prior authorization is limited to 4 weeks of therapy.

Continued coverage will be dependent upon documentation to support clinical response and lack of adverse effects to therapy.

Maximum allowable duration of therapy is 12 months.

Dose is limited to 2mg daily in divided doses.

**Exclusion Criteria:**

Lubiprostone (Amitiza) and alosetron (Lotronex) are not covered under the following situations:

- patients not meeting Rome II criteria and other criteria listed
- patients with medical contraindications for use
- treatment of mixed or constipation-predominant IBS for alosetron
- evidence of anatomic or biochemical abnormalities of the gastrointestinal tract, endocrine or metabolic conditions, neurological conditions, including but not limited to:

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- a. ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state,
  - b. intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions (scar tissue), anal fissures, diverticulosis, diverticulitis, tumors or cancer narrowing the intestine, colorectal stricture, Crohn's disease, ulcerative colitis, gastroparesis, symptomatic gallbladder disease,
  - c. neurological disorders: multiple sclerosis, Parkinson's disease, intestinal pseudo-obstruction, stroke, spinal cord injury,
  - d. metabolic and endocrine: diabetes, underactive/overactive thyroid gland, uremia, hypercalcemia,
  - e. systemic disorders: amyloidosis, lupus, scleroderma
- dietary or drug induced diarrhea or constipation
  - patients at an increased risk of colitis
  - patients on contraindicated medications (i.e. fluvoxamine – alosetron)
  - lubiprostone is not currently approved for use in constipation predominant IBS, post operative bowel dysfunction or opioid-induced bowel dysfunction
  - women who could become pregnant should have a negative pregnancy test prior to beginning therapy with lubiprostone and should be capable of complying with effective contraceptive measures since lubiprostone is a Pregnancy category C.
  - Doses exceeding the FDA package labeling

**Coverage Duration:** Initial approval limited to 4 weeks. Maximum allowable duration of therapy is 12 months