COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: September 1, 2022 Notification Posted:

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Revisions are effective the first of the month following a 45-day notification and comment period.

UM PROGRAM CRITERIA REVISED			
Lotronex (alosetron)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Lotronex	1. Conventional therapy for fail first criteria defined.		

Prior Authorization Approval Criteria

Lotronex (alosetron)

Generic name: alosetron
Brand name: Lotronex
Medispan GPI: 5255401510 **** MON
Medication class: 5-HT3 Receptor Antagonist
FDA-approved uses: **Females with severe diarrhea-predominant irritable bowel syndrome (IBS-D)**

Usual dose range:
IBS-D Initial: 0.5mg twice daily Maintenance: 1mg twice daily

Duration of Authorization:
Initial: 3 months
Ongoing: 12 months

Estimated Cost:

Criteria for use for IBS-D

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.

- Grandfather criteria allowed
    - Please see policy and procedure "*14 – Grandfather Status Authorization*" for additional information.
- Patient is clinically diagnosed with severe diarrhea-predominant irritable bowel syndrome (IBS-D) who have chronic IBS symptoms (generally lasting 6 months or longer), have had anatomic or biochemical abnormalities of the GI tract excluded, and who have not responded adequately to conventional therapy to include:
    - Antidiarrheal agents
    - Antispasmodics
    - Low dose tricyclic antidepressants
- Must be female.
- Must be 18 years of age or older.
- Must be prescribed by a physician who has enrolled in the Prometheus Prescribing Program for Lotronex.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Chart notes evaluating the safety and efficacy from within the prior 12 months are required for reauthorization.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Do not initiate in patients with constipation.
- Patients with history of chronic or severe constipation or sequelae from constipation.
- Patients with history of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohn disease, ulcerative colitis.
- Patients with history of severe hepatic impairment.
- Patients with history of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state.
- Coadministration with fluvoxamine.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.

Special Considerations:

- Discontinue immediately in patients who develop constipation; infrequent but serious complications of constipation have resulted in hospitalization, and rarely, blood transfusion, surgery, or death have been reported (obstruction, ileus, perforation [rare], impaction, toxic megacolon, secondary bowel ischemia). Constipation is a frequent, dose-related side effect; risk for complications from constipation may be increased in elderly, debilitated patients, or with concurrent use of other medications which decrease GI motility. Nonsevere constipation may be managed by temporarily interrupting therapy and decreasing the dose. Do not initiate in patients with constipation.
- Ischemic colitis has been reported during treatment without warning. Discontinue and evaluate immediately in patients who experience rectal bleeding, bloody diarrhea, or a sudden worsening of abdominal pain, and do not restart therapy if ischemic colitis is diagnosed.
- Only indicated for women with severe diarrhea-predominant IBS who have not responded adequately to conventional therapy who have chronic IBS symptoms (lasting at least 6 months) and are without anatomic or biochemical abnormalities of the GI tract. Severe diarrhea-predominant IBS includes at least 1 of the following: frequent and severe abdominal pain/discomfort, frequent bowel urgency or fecal incontinence, and disability or restriction of daily activities due to IBS.
- Use with caution in debilitated patients due to increased risk of complications from constipation.

References:

1. Lotronex (alosetron) [prescribing information]. Roswell, GA: Sebela Pharmaceuticals Inc; April 2019.

MedOne P&T Committee approval: Date: 2-9-2000

Adopted: 2-9-2000
Revised: 8-27-2021
7-5-2022

Updates:

8-27-21
1. Grandfathering criteria requirements defined.

7-5-22
1. Conventional therapy for fail first criteria defined.

Effective Date (most recent revisions): 9-1-22

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