Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization Number: 07.047
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Purpose:
To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived.

Background Information:

Medication Summary

- Lotronex is indicated for the treatment of Irritable Bowel Syndrome (IBS) in female Members whose predominant bowel symptom is diarrhea.
- Lotronex is an oral selective serotonin 5-HT3 receptor antagonist.
- Manufacturer voluntarily removed Lotronex from the market in November 2000, but in June 2002, the medication was reintroduced. A Box Warning was placed on the label indicating that Members must first have a follow-up exam before refills could be provided. Members and physicians must sign a risk-benefit statement and agree to adhere to the instructions in the manufacturer’s package insert prior to the medication being prescribed.
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Background Information, continued:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Coverage Guidelines

- Member must be eligible for benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Male gender (only indicated for use in females);
- History of chronic or severe constipation or with a history of sequelae from constipation;
- History of intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions;
- History of ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state;
- Current or history of Crohn’s disease or ulcerative colitis;
- Active diverticulitis or history of diverticulitis;
- Impaired mental capacity that limits ability to understand or comply with the Patient-Physician Agreement;
- Known hypersensitivity to any component of the product;
- Absence of the Physician-Patient Agreement form prior to receiving their prescription.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
Procedure:

1.0  Request for initial therapy with Lotronex for diarrhea predominant IBS requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1  Diagnosis of diarrhea predominant IBS with severe symptoms as evidenced by one (1) or more of the following:

1.1.1  Frequent/severe abdominal discomfort or pain;

1.1.2  Frequency bowel urgency or fecal incontinence (greater than 3 bowel movements per day);

1.1.3  Disability or restriction of daily activities due to IBS; OR

1.1.3  Two (2) or more of the following present at least 25% of the time:

1.1.3.1  Change in stool frequency (more than three (3) bowel movements per day or fewer than three (3) bowel movements per week;

1.1.3.2  Noticeable difference in stool form (hard, loose and watery stools or poorly formed stools;

1.1.3.3  Passage of mucous in stools;

1.1.3.4  Bloating or feeling of abdominal distension;

1.1.3.5  Altered stool passage (sensations of incomplete evacuation, straining or urgency);

1.2  Member must be 18 years of age or older;

1.3  Prescriber must be enrolled in the manufacturer-sponsored prescribing program for Lotronex;

1.4  Member’s must have documented continuous or recurrent symptoms for at least six (6) months;
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Procedure, continued:

1.0 Request for initial therapy with Lotronex for diarrhea predominant IBS requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

1.5 Member must have tried and failed at least a one (1) month trial of conventional therapy, to include at least two (2) of the following treatment regimens:

1.5.1 Dietary changes (including fiber), or stress reduction, or behavioral changes;
1.5.2 Antidiarrheals up to the recommended daily maximum dosages (loperamide, diphenoxylate/atropine);
1.5.3 Antispasmodics (dicyclomine, Donnatal, hyoscyamine);
1.5.4 Tricyclic antidepressants (amitriptyline, desipramine);
1.5.5 Bulking agents or bile acid sequestrant (psyllium, polycarbophil, methylcellulose, cholestyramine);

1.6 If the Member meets all of the above criteria, may approve Lotronex up to a maximum dose of 2mg per day for up to three (3) months.

2.0 Request for continuation of therapy beyond initial authorization period for diarrhea predominant IBS requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying all of the following:

2.1 Reduction in Member’s signs and symptoms of IBS (i.e., reduction in abdominal pain, improvement in frequency of bowel movements); AND

2.2 No development of any adverse effects (such as constipation or ischemic colitis) or contraindications/exclusions that would prevent continuation;

2.3 If criteria are met, up to a maximum dose of 2mg per day of Lotronex may be approved for one (1) year of therapy.
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