Linaclotide in Irritable Bowel Syndrome With Constipation
Criteria for Use
July 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. Local adjudication should be used until updated guidance and/or CFU are developed by the National PBM. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE OUTSIDE THE RECOMMENDATIONS SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If ANY of the following are selected, the patient will NOT meet criteria for linaclotide.

- ☐ Mechanical gastrointestinal obstruction, known or suspected
- ☐ Age less than 18 years
- ☐ Presence of severe or frequent diarrhea

Note: For purposes of these criteria and as causes of chronic constipation, irritable bowel syndrome (IBS) excludes drug-induced chronic constipation and chronic constipation due to neurogenic and non-neurogenic disorders.

Inclusion Criteria

All the following criteria must be selected to meet criteria.

- ☐ Men or women 18 years or older with irritable bowel syndrome with constipation (IBS-C)
- ☐ Intolerance or inadequate response to a 1-month trial of either PEG-3350 powder for oral solution or other osmotic laxative,^1 unless there is a contraindication or risk factor(s) for serious adverse event(s)

GI consultation (including e-consult) is highly recommended prior to using linaclotide for IBS-C.

Additional Inclusion Criteria

ONE of the following criteria must be selected to meet criteria.

- ☐ For men: Intolerance or inadequate response to a 1-month trial of plecanatide (3 mg once daily) unless there is a contraindication or risk factor(s) for serious adverse event(s).
- ☐ For women: Intolerance or inadequate response to a 1-month trial of lubiprostone (8 mcg twice daily) unless there is a contraindication or risk factor(s) for serious adverse event(s). Use of lubiprostone is off-label for IBS-C in men.

Other Justification

- ☐ _____

Footnotes

1 Examples of osmotic laxatives: lactulose, sorbitol, magnesium citrate, magnesium hydroxide, glycerin rectal suppositories. During the 1-month trial, escalation/titration of therapy up to bowel-prep doses of PEG-3350 may be considered case by case to achieve the desired response.

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