

Prucalopride in Chronic Idiopathic Constipation Criteria for Use July 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

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. 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 prucalopride.

- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the GI tract (e.g., Crohn's disease, ulcerative colitis, toxic megacolon / megarectum)
- Untreated or unstable depression or suicidality.
- End-stage renal disease requiring dialysis.
- Age less than 18 years
- Presence of severe or frequent diarrhea

Note: For purposes of these criteria and as causes of chronic constipation, chronic idiopathic constipation (CIC) 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 CIC
- Intolerance or inadequate response to a 1-month trial of at least one bulk forming laxative (e.g., psyllium, oxidized cellulose, calcium polycarbophil) with fluids, unless there is a contraindication or risk factor(s) for serious adverse event(s)
- Intolerance or inadequate response to a 1-month trial of either PEG-3350 powder for oral solution (17 g twice daily) or other osmotic laxative,¹ unless there is a contraindication or risk factor(s) for serious adverse event(s)
- Intolerance or inadequate response to a 1-month trial of lubiprostone (24 mcg twice daily) unless there is a contraindication or risk factor(s) for serious adverse event(s)

GI consultation is highly recommended to diagnose and evaluate CIC.

Other Justification

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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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