Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 21, 2021 July 18, 2023, March 26, 2024, December 20, 2024

Constipation Treatment Agents

PREFERRED MEDICATION	NON-PREFERRED MEDICATION	AUTOMATED PRIOR AUTHORIZATION MEDICATION (trial and failure to lactulose required)
Lactulose 10 gm/15 mL solution	Amitiza® (lubiprostone)	Linzess® (linaclotide)
Lactulose 20 gm/30 mL solution	Ibsrela® (tenapanor)*	Movantik® (naloxegol)
	Motegrity® (prucalopride)	Relistor® (methylnaltrexone)
	Symproic® (naldemedine)	Trulance ® (plecanatide)

*Ibsrela has drug-specific criteria

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- For the treatment of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C):
  - The patient has a confirmed diagnosis of CIC or IBS-C.
  - Patient must have a documented history (within the past month) of trial and failure or intolerance to Lactulose.
  - Patient has tried and failed one of the preferred agents [e.g., Linzess® (linaclotide) and Trulance® (plecanatide)] or have a medical reason as to why the patient is unable to use the preferred product.
- For the treatment of opioid induced constipation (OIC):
  - The patient must have a documented history (within the past month) of an advanced illness (e.g., cancer) that requires the chronic use of opioids OR patient has a confirmed diagnosis of OIC with chronic non-cancer pain.
  - Patient must have a documented history (within the past month) of trial and failure or intolerance to Lactulose.
  - Patient has tried and failed one of the preferred agents [e.g., Movantik® (naloxegol) and Relistor® (methylnaltrexone)] or have a medical reason as to why the patient is unable to use the preferred product.
- Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines.

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DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/