

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, March 18, 2025

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) injectable formulations
	Symproic [®] (naldemedine)	Trulance [®] (plecanatide)
	Relistor[®] (methylnaltrexone) tablets	

*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) **injectable formulations**] 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.

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

DOSING AND ADMINISTRATION:

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