

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	GI Motility Agents, Chronic, PDL Edit
<b>First Implementation Date:</b>	April 6, 2017
<b>Revised Date:</b>	December 17, 2020
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Opioid-Induced Constipation (OIC) is a common adverse effect of opioid therapy. A prophylactic bowel regimen is recommended when initiating opioid therapy. Amitiza<sup>®</sup> is indicated for OIC in adults with chronic non-cancer pain, as well as Movantik<sup>®</sup>, an opioid receptor antagonist drug. Relistor<sup>®</sup> tablets are also approved for OIC. Symproic<sup>®</sup> (also structurally related to naloxone) is the newest product to treat OIC. Relistor injection is indicated for treatment of OIC in patients with advanced illness (e.g. palliative care). Therapy with these agents is significantly more costly than with older medications.

Chronic Idiopathic Constipation (CIC) is generally defined as infrequent and difficult passage of stool. Constipation secondary to other diseases (e.g. Parkinson's, spinal cord injury) is generally not considered CIC. FDA-indicated products Linzess<sup>®</sup>, Amitiza<sup>®</sup> and Trulance<sup>®</sup> increase fluid motility in the intestinal tract to alleviate symptoms associated with CIC.

Irritable bowel syndrome (IBS) is a functional bowel disorder that can be characterized by predominantly constipation (IBS-C) or diarrhea (IBS-D), or symptoms may be mixed (IBS-M). Drugs that are helpful for CIC are also beneficial in treating IBS-C. Amitiza is approved for treatment of IBS-C in women-only. Lotronex<sup>®</sup> and alosetron are indicated for the treatment of severe IBS-D in women-only who have failed conventional therapy. Viberzi<sup>®</sup> is an opioid receptor agonist and which is also approved to treat IBS-D.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Amitiza®</li> <li>• Linzess®</li> <li>• Movantik®</li> </ul>	<ul style="list-style-type: none"> <li>• Alosetron</li> <li>• Lotronex®</li> <li>• Motegrity™</li> <li>• Relistor®</li> <li>• Symproic®</li> <li>• Trulance®</li> <li>• Viberzi®</li> <li>• Zelnorm™</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: GI Motility Agents, Chronic
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Documented compliance on a current therapy regimen **OR**
- For agents with diarrhea indications:
  - Therapeutic trial on at least **1** anti-diarrheal product **AND**
  - For Lotronex: Documented diagnosis of IBS with diarrhea as primary bowel symptom (female)
  - For Viberzi: Documented diagnosis of IBS with severe diarrhea as primary bowel symptom
- For agents with constipation indications:
  - Therapeutic trial on at least **2** different covered laxative preparations **AND**
  - Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents:
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents **AND**
  - **For Motegrity: Documented diagnosis of Chronic Idiopathic Constipation**
  - For Movantik, Relistor, or Symproic:
    - Participant is currently on opioid therapy (1 claim in the last 45 days) **AND**
    - Documented diagnosis of drug induced constipation **in adults with chronic non-cancer pain (Movantik/Symproic) or adults with advanced disease (Relistor)**
  - For Linzess or Trulance:
    - Documented diagnosis of Chronic Idiopathic Constipation **OR**
    - Documented diagnosis of Irritable Bowel Syndrome with Constipation (male and female)
  - For Amitiza:
    - Documented diagnosis of Chronic Idiopathic Constipation **OR**
    - Documented diagnosis of Irritable Bowel Syndrome with Constipation (female) **OR**
    - Documented diagnosis of Opioid-Induced Constipation in adults with chronic non-cancer pain **AND** participant is currently on opioid therapy (1 claim in the last 45 days)
  - For Zelnorm:
    - Documented diagnosis of Irritable Bowel Syndrome with Constipation (female) **AND**
    - Participant aged < 65 years

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitations on the following:

Drug Description	Generic Equivalent	Maximum Dosing Limitations
AMITIZA 8MCG CAPSULE	LUBIPROSTONE	2 capsules per day
AMITIZA 24MCG CAPSULE	LUBIPROSTONE	2 capsules per day
LINZESS 72 MCG CAPSULE	LINACLOTIDE	1 capsule per day
LINZESS 145 MCG CAPSULE	LINACLOTIDE	1 capsule per day
LINZESS 290 MCG CAPSULE	LINACLOTIDE	1 capsule per day
LOTRONEX 0.5MG TABLET	ALOSETRON HCL	2 tablets per day
MOTEGRITY 1 MG TABLET	PRUCALOPRIDE SUCCINATE	1 tablet per day
MOTEGRITY 2 MG TABLET	PRUCALOPRIDE SUCCINATE	1 tablet per day
MOVANTIK 12.5 MG TABLET	NALOXEGOL OXALATE	1 tablet per day
MOVANTIK 25 MG TABLET	NALOXEGOL OXALATE	1 tablet per day
RELISTOR 150 MG TABLET	METHYLNALTREXONE BROMIDE	3 tablets per day
SYMPROIC 0.2 MG TABLET	NALDEMEDINE	1 tablet daily
TRULANCE 3 MG TABLET	PLECANATIDE	1 tablet daily
VIBERZI 75 MG TABLET	ELUXADOLINE	3 tablets daily
VIBERZI 100 MG TABLET	ELUXADOLINE	2 tablets daily
ZELNORM 6 MG TABLET	TEGASEROD	2 tablets daily

## Required Documentation

Laboratory Results:   
 MedWatch Form:

Progress Notes:   
 Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List Edit)  
 Rule Type: PDL

## Default Approval Period

1 year

## References

1. Evidence-Based Medicine and Fiscal Analysis: "GI Motility Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; November 2020.
2. Evidence-Based Medicine Analysis: "Gastrointestinal Motility Agents", UMKC-DIC; August 2020.
3. Symproic® (naldemedine) [package insert]. Florham Park, NY: Shionogi Inc., March 2017.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
5. USPDI, Micromedex; 2020.
6. Drug Facts and Comparisons On-line; 2020.
7. Trulance® (plecanatide) [package insert]. New York, NY: Synergy Pharmaceuticals Inc., January 2018.

SmartPA PDL Proposal Form

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