SmartPA Criteria Proposal

Drug/Drug Class:	GI Motility Agents, Chronic PDL Edit
First Implementation Date:	April 6, 2017
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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® is indicated for OIC in adults with chronic non-cancer pain, as well as Movantik®, an opioid receptor antagonist drug. Relistor® tablets are also approved for OIC. Symproic® (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®, Amitiza® and Trulance® 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® and alosetron are indicated for the treatment of severe IBS-D in women-only who have failed conventional therapy. Viberzi® 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
	• Amitiza® • Linzess® • Movantik®	• Alosetron • Lotronex® • Lubiprostone • Motegrity® • Relistor® • Symproic® • Trulance® • Viberzi® • Zelnorm™

Type of Criteria: ☒ **Increased risk of ADE** ☒ **Preferred Drug List**
☒ **Appropriate Indications** ☐ **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 covered anti-diarrheal product **AND**
  - For Lotronex: Documented diagnosis of irritable bowel syndrome with diarrhea as primary bowel symptom (female)
  - For Viberzi: Documented diagnosis of irritable bowel syndrome 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
  - 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	Max 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 0.5 MG TABLET	ALOSETRON HCL	2 tablets per day
LOTRONEX 1 MG 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:		Progress Notes:	X
MedWatch Form:		Other:	

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “GI Motility Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: “Gastrointestinal Motility Agents”, UMKC-DIC; August 2021.
- USPDI, Micromedex; 2021.
- Drug Facts and Comparisons On-line; 2021.