SmartPA Criteria Proposal

Drug/Drug Class:	GI Motility Agents, Chronic PDL Edit
First Implementation Date:	April 6, 2017
Revised Date:	September 21, 2023
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®, Movantik®, Relistor®, and Symproic® are all approved to treat OIC in patients with chronic non-cancer pain. Relistor injection has an additional indication 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, Ibsrela®, Linzess®, and Trulance® are approved for treatment of IBS-C. Lotronex® is 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 • Ibsrela® • Lotronex® • Lubiprostone • Motegrity® • Relistor® • Symproic® • Trulance® • Viberzi®

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**
  - For non-preferred agents: 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 documented diagnosis of chronic idiopathic constipation: Claim is for Amitiza, Linzess, Motegrity, or Trulance
  - For documented diagnosis of irritable bowel syndrome with constipation:
    - Claim is for Amitiza, Linzess or Trulance **OR**
    - Claim for Ibsrela: documented therapeutic trial of 2 preferred agents and 1 non-preferred agent
  - For documented diagnosis of opioid-induced constipation:
    - Participant is currently on opioid therapy (1 claim in the past 45 days) **AND**
    - Claim is for Amitiza, Movantik, Relistor, or Symproic
  - **For documented diagnosis of gastroparesis:**
    - **Claim is for Motegrity AND**
    - **Clinical consultant review required**

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
IBSRELA 50 MG TABLET	TENAPANOR HCL	2 tablets 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 per day
TRULANCE 3 MG TABLET	PLECANATIDE	1 tablet per day
VIBERZI 75 MG TABLET	ELUXADOLINE	3 tablets per day
VIBERZI 100 MG TABLET	ELUXADOLINE	2 tablets per day

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: “Therapeutic Class Review: GASTROINTESTINAL: IBS-C/CIC Agents”, Gainwell Technologies; Last updated October 20, 2022.
- 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: “GI Motility Agents”, UMKC-DIC; August 2022.
- Evidence-Based Medicine Analysis: “Opioid-Induced Constipation”, UMKC-DIC; October 2022.
- USPDI, Micromedex; 2022.
- Drug Facts and Comparisons On-line; 2022.
- Carbone F, Van den Houte K, Clevers E, Andrews CN, Papathanasopoulos A, Holvoet L, Van Oudenhove L, Caenepeel P, Arts J, Vanuytsel T, Tack J. Prucalopride in Gastroparesis: A Randomized Placebo-Controlled Crossover Study. Am J Gastroenterol. 2019 Aug;114(8):1265-1274. PMID: 31295161.