

	Johns Hopkins Health Plans <b>Pharmacy Public          Pharmacy Management Drug Policies</b>	<i>Policy Number</i>	MEDS044	
		<i>Effective Date</i>	01/17/2024	
		<i>Approval Date</i>	01/17/2024	
	<i>Subject</i>	<b>Miscellaneous Constipation Agents: Lubiprostone (Amitiza),          Linzess, Trulance, Motegrity, Ibsrela</b>	<i>Supersedes Date</i>	N/A
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This document applies to the following Participating Organizations:

Priority Partners

**Keywords:** Amitiza, Ibsrela, Linzess, Lubiprostone, Motegrity, Trulance

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## **I. POLICY**

- A. Amitiza (lubiprostone), Linzess (linaclotide), Trulance (plecanatide), Motegrity (Prucalopride) and will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
- PPMCO members are subject to the Priority Partners formulary, available at [www.ppmco.org](http://www.ppmco.org).
  - USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: [http://pec.ha.osd.mil/formulary\\_search.php?submenuheader=1](http://pec.ha.osd.mil/formulary_search.php?submenuheader=1)

## **II. POLICY CRITERIA**

- A. **Lubiprostone** (generic of Amitiza) may be approved for patients meeting the following:
- Chronic Idiopathic Constipation (CIC):
    - Patient is 18 years of age or older
    - Documentation of a history of constipation, defined as less than three solid bowel movements (SBMs) per week for a duration of three months or greater
    - Documented trial of at least two formulary laxatives from two different therapy classes for at least one month each
  - Opioid-Induced Constipation:
    - Patient is 18 years of age or older
    - Documentation of diagnosis of constipation due to continuous use of a long-acting opioid agent (e.g. Oxycontin, fentanyl patches, etc.)
    - Documentation of diagnosis of chronic non-cancer pain that precludes the discontinuation of the long-acting opioid agent
    - Documented trial and inadequate response to 3 or more conventional formulary laxatives for at least one month each

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3. Irritable Bowel Syndrome (IBS):
  - a. Patient is female and 18 years of age or older
  - b. Documentation of diagnosis of constipation-predominant irritable bowel syndrome
  - c. Documented trial of at least two agents to treat IBS from two different therapy classes for at least one month each
- B. **Linzess** may be approved for patients meeting the following:
  1. Chronic Idiopathic Constipation (CIC):
    - a. Patient is 18 years of age or older
    - b. Documentation of a history of constipation, defined as less than three solid bowel movements (SBMs) per week for a duration of three months or greater
    - c. Documented trial of at least two formulary laxatives from two different therapy classes for at least one month each
    - d. Documented trial of lubiprostone
  2. Irritable Bowel Syndrome (IBS):
    - a. Patient is 18 years of age or older
    - b. Documentation of diagnosis of constipation-predominant irritable bowel syndrome
    - c. Documented trial of at least two agents to treat IBS from two different therapy classes for at least one month each
    - d. \*Additional gender-specific requirement:
      - I. If patient is female, trial and inadequate response to lubiprostone is also required
  3. Functional Constipation (FC):
    - a. Patient is between 6 and 17 years of age
    - b. Documentation of functional constipation
    - c. Documentation of less than 3 spontaneous bowel movements per week in the absence of laxative, enema, or suppository use, as well as at least one of the following for at least 2 months:
      - I. History of stool withholding or excessive voluntary stool retention
      - II. History of painful or hard bowel movements
      - III. History of large diameter stools that may obstruct the toilet
      - IV. Presence of a large fecal mass in the rectum
      - V. At least 1 episode of fecal incontinence per week
    - d. Documented trial of at least two formulary laxatives from two different therapy classes for at least one month each
- C. **Trulance** may be approved for patients meeting the following:
  1. Chronic Idiopathic Constipation (CIC):
    - a. Patient is 18 years of age or older
    - b. Documentation of a history of constipation, defined as less than three solid bowel movements (SBMs) per week for a duration of three months or greater
    - c. Documented trial of at least two formulary laxatives from two different therapy classes for at least one month each
    - d. Documented trial of lubiprostone
  2. Irritable Bowel Syndrome (IBS):
    - a. Patient is 18 years of age or older
    - b. Documentation of diagnosis of constipation-predominant irritable bowel syndrome

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- c. Documented trial of at least two agents to treat IBS from two different therapy classes for at least one month each
- d. \*Additional gender-specific requirement:
  - I. If patient is female, trial and inadequate response to lubiprostone is also required
- D. **Motegrity** may be approved for patients meeting the following:
  - 1. Chronic Idiopathic Constipation (CIC):
    - a. Patient is 18 years of age or older
    - b. Documentation of a history of constipation, defined as less than three solid bowel movements (SBMs) per week for a duration of three months or greater
    - c. Documented trial of at least two formulary laxatives from two different therapy classes for at least one month each
    - d. Documented trial of lubiprostone
- E. **Ibsrela** may be approved for patients meeting the following:
  - 1. Irritable Bowel Syndrome (IBS):
    - a. Patient is 18 years of age or older
    - b. Documentation of diagnosis of constipation-predominant irritable bowel syndrome
    - c. Documented trial of at least two agents to treat IBS from two different therapy classes for at least one month each
    - d. \*Additional gender-specific requirement:
      - I. If patient is female, trial and inadequate response to lubiprostone is also required

### **III. AUTHORIZATION PERIOD/LIMITATIONS**

- A. Initial approval of lubiprostone (generic of Amitiza) will be restricted to 6 months of therapy, dosed as either 8 mcg twice daily for IBS, or 24 mcg twice daily for CIC or OIC.
- B. Initial approval of Linzess will be restricted to 6 months of therapy, dosed as 290 mcg once daily for IBS, either 145 mcg or 72mcg once daily for CIC, or 72mcg once daily for FC.
- C. Initial approval of Trulance will be restricted to 6 months of therapy, dosed as 3mg once daily for CIC or IBS.
- D. Initial approval of Motegrity will be restricted to 6 months of therapy, dosed as 2mg once daily for CIC.
- E. Initial approval of Ibsrela will be restricted to 6 months of therapy, dosed as 50 mg twice daily for IBS.
- F. Approval for continuation of therapy can be extended at 12-month intervals with clinical documentation showing the patient has had a beneficial response to treatment.

### **IV. EXCLUSIONS**

- A. Lubiprostone (generic of Amitiza), Linzess, Trulance, Motegrity and Ibsrela are not approved for the following:
  - 1. ANY indications or uses that are not FDA-approved, or guideline-supported, such as:
    - a. Treatment of acute constipation (less than three months duration)
    - b. Treatment of diarrhea-predominant IBS
    - c. Use in pediatric patients less than 18 years of age (except for Linzess when used for FC)
  - 2. Concurrent use
- B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

### **V. REFERENCES**

- 1. Amitiza [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; November 2020

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2. Linzess [prescribing information]. Madison, NJ: Allergan USA Inc; June 2023
3. Trulance [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Bausch Health US, LLC; April 2021
4. Motegrity [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America; November 2020.
5. Ibsrela [prescribing information]. Waltham, MA: Ardelyx Inc; April 2022.
6. Chang L, Sultan S, Lembo A, Verne GN, Smalley W, Heidelbaugh JJ. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Constipation. *Gastroenterology*. 2022 Jul;163(1):118-136.
7. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. *Gastroenterology*. 2019 Jan;156(1):218-226.

## VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Updated indications for Amitiza; Addition of criteria for Linzess; updated authorization duration
02/02/2017	Clarified dosing for Linzess based on the FDA-approved labeling for CIC dosing
04/12/2017	Clarified CIC criteria verbiage for Amitiza
07/19/2017	Added clinical criteria for Trulance
07/27/2017	Updated Exclusions section regarding physician samples
02/19/2019	Added IBS with constipation to the criteria for Trulance based on updated FDA-approved labeling
07/17/2019	Revised clinical criteria for Amitiza based on AGA guidelines, and added clinical criteria for Motegrity
8/20/2019	Clarified clinical criteria for Amitiza
07/20/2022	Added clinical criteria for Ibsrela; updated layout
07/19/2023	Clinical criteria update for Linzess
01/17/2024	Updated criteria for lubiprostone

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