

Reference number(s)
843-A, 1023-A

# Initial Prior Authorization

## Linzess

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Linzess	linaclotide

### Indications

#### FDA-approved Indications

Linzess is indicated for the treatment of:

- irritable bowel syndrome with constipation (IBS-C) in adults
- chronic idiopathic constipation (CIC) in adults
- functional constipation (FC) in pediatric patients 6 to 17 years of age

### Coverage Criteria

#### Chronic Idiopathic Constipation (CIC)

Authorization may be granted when the requested drug is being prescribed for the treatment of chronic idiopathic constipation (CIC) in an adult patient.

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## Functional Constipation (FC)

Authorization may be granted when the requested drug is being prescribed for the treatment of functional constipation (FC) when the following criteria is met:

- The request is for a pediatric patient 6 to 17 years of age.

## Irritable Bowel Syndrome with Constipation (IBS-C)

Authorization may be granted when the requested drug is being prescribed for the treatment of irritable bowel syndrome with constipation (IBS-C) in an adult patient.

## Duration of Approval (DOA)

- 843-A: DOA: 12 months
- 1023-A: DOA: 36 months

## References

1. Linzess [package insert]. North Chicago, IL: AbbVie, Inc.; Boston, MA: Ironwood Pharmaceuticals, Inc.; June 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed August 1, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/01/2024).

## Document History

Written by: UM Development (CT)

Date Written: 10/2012

Revised: 08/2013, 08/2014; (JH) 08/2015; (KM) 08/2016 (removed safety question); (DS) 08/2017 (no clinical changes); (JG) 09/2018 (no clinical changes); (DS) 09/2019 (no clinical changes; combined criteria; removed MDC); (PM) 08/2020 (no clinical changes), 09/2021 (no clinical changes); (VLS) 09/2022 (no clinical changes), 06/2023 (added FC indication); (SS) 09/2023 (no clinical changes); (DMH) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (LCB) 10/2012; (LMS) 08/2013, 08/2014; (MC) 08/2015; (ME) 08/2016; (CHART) 09/26/2019; 09/24/2020, 09/30/2021, 09/22/2022, 06/22/2023, 09/28/2023, 09/26/2024

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External Review: 10/2012, 12/2013, 12/2014, 12/2015, 12/2016, 12/2017, 12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 08/2023 (FYI), 12/2023, 12/2024

<b>CRITERIA FOR APPROVAL</b>			
1	Is the requested drug being prescribed for the treatment of irritable bowel syndrome with constipation (IBS-C) in an adult patient? [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Is the requested drug being prescribed for the treatment of chronic idiopathic constipation (CIC) in an adult patient? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Is the requested drug being prescribed for the treatment of functional constipation (FC)? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Is the request for a pediatric patient 6 to 17 years of age? [No further questions]	Yes	No

<b>Mapping Instructions</b>			
	<b>Yes</b>	<b>No</b>	<b>DENIAL REASONS</b>
<b>1.</b>	Approve, 36 Months	Go to 2	
<b>2.</b>	Approve, 36 Months	Go to 3	
<b>3.</b>	Go to 4	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for A) Irritable bowel syndrome with constipation (IBS-C) in an adult, B) Chronic idiopathic constipation (CIC) in an adult, and C) Functional constipation (FC) in a child. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your

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			<p>review.</p> <p>[Short Description: Diagnosis]</p>
4.	Approve, 36 Months	Deny	<p>Your plan only covers this drug if you are between 6 and 17 years old. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Age]</p>