

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Linzess (linaclotide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

***\*Maryland Medicaid – See State Specific Mandates below***

Medications	Quantity Limit
Linzess (linaclotide)	May be subject to quantity limit

### **APPROVAL CRITERIA**

Requests for Linzess (linaclotide) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older;

**AND**

- II. Individual has a diagnosis of chronic idiopathic constipation (CIC);

**OR**

- III. Individual has a diagnosis of irritable bowel syndrome with constipation (IBS-C);

**AND**

- IV. Individual must have a previous trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of or insufficient response to two laxatives [e.g. polyethylene glycol (generic MiraLax), bisacodyl (Dulcolax), senna (Ex-lax)] (AGA 2013, 2019).

Linzess (linaclotide) may **not** be approved for the following:

- I. Individual has a known or suspected mechanical gastrointestinal obstruction.

**Note:** Linzess (linaclotide) has a black box warning for pediatric risk. Use is contraindicated in individuals up to 6 years of age. Use should be avoided in individuals 6 through 17. Linzess has caused deaths in young juvenile mice at clinically relevant adult doses.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Maryland		Trial of polyethylene glycol (PEG) is not required

**Key References:**

1. American Gastroenterological Association, Bharucha AE, Dorn SD, Lembo A, Pressman A. American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013 Jan;144(1):211-7. Available from: [http://www.gastrojournal.org/article/S0016-5085\(12\)01545-4/pdf](http://www.gastrojournal.org/article/S0016-5085(12)01545-4/pdf). Accessed on: January 9, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 8, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.