



**LINZESS
(linaclotide)**

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Linzess (linaclotide) is a guanylate cyclase-C (GC-C) agonist indicated in adults with irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), and also in patients 6 to 17 years of age with functional constipation (FC). Activation of GC-C results in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevation of intracellular cGMP stimulates secretion of chloride and bicarbonate into the intestinal lumen, mainly through activation of the cystic fibrosis transmembrane conductance regulator (CFTR) ion channel, resulting in increased intestinal fluid and accelerated transit. In animal models, Linzess has been shown to both accelerate GI transit and reduce intestinal pain (1).

Regulatory Status

FDA-approved indications: Linzess is a guanylate cyclase-C agonist indicated for treatment of: (1)

1. Irritable bowel syndrome with constipation (IBS-C) in adults.
2. Chronic idiopathic constipation (CIC) in adults.
3. Functional constipation (FC) in pediatric patients 6 to 17 years of age.

Linzess has a boxed warning regarding the risk of serious dehydration in pediatric patients. Linzess is contraindicated in pediatric patients less than 2 years of age (1).

Linzess is also contraindicated in patients with known or suspected mechanical gastrointestinal obstruction (1).

Linzess has a warning for severe diarrhea. If severe diarrhea occurs, suspend dosing, and rehydrate patient (1).

The safety and effectiveness in pediatric patients less than 18 years of age with IBS-C and CIC have not been established. The safety and effectiveness in pediatric patients less than 6 years of age with FC have not been established (1).

Summary

Linzess (linaclotide) is a guanylate cyclase-C (GC-C) agonist indicated in adults with irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), and also in patients



**BlueCross.
BlueShield.**

Federal Employee Program.

LINZESS (linaclotide)

6 to 17 years of age with functional constipation (FC). Linzess has a boxed warning regarding the risk of serious dehydration in pediatric patients. Linzess is contraindicated in pediatric patients less than 2 years of age. Linzess has a warning for severe diarrhea. If severe diarrhea occurs, suspend dosing, and rehydrate patient (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Linzess while maintaining optimal therapeutic outcomes.

References

1. Linzess [package insert]. North Chicago, IL: AbbVie, Inc.; June 2023