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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	June 16, 2023
Subject:	Vibrant System	**Page:**	1 of 5

Last Review Date: December 13, 2024

Vibrant System

Description

Vibrant System

Background
The Vibrant System is comprised of two components: a pod and a single use capsule. The pod activates the capsule using radio frequency (RF) communication. After activation, the capsules are taken orally. After a pre-programmed activation delay, the capsules begin to vibrate. The marketed device will have an activation delay of 14 hours. As they pass through the gastrointestinal tract, the capsules vibrate for four pre-programmed periods of 100 min, 120 min, 100 min, 180 min. It takes about three days for the capsules to pass through the gastrointestinal tract, at which point they are excreted in a bowel movement (1).

Regulatory Status
FDA-approved indication: The Vibrant System is an orally administered capsule that is indicated for the treatment of adults with chronic idiopathic constipation who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month (1).

The Vibrant capsules are contraindicated for use under the following conditions (1):

- History of complicated/obstructive diverticular disease
- History of intestinal or colonic obstruction, or suspected intestinal obstruction
- Clinical evidence of current and significant gastroparesis

- History of significant gastrointestinal disorder, including any form of inflammatory bowel disease or gastrointestinal malignancy (celiac disease is accepted if the subject has been treated and is in remission), and/or anal fissures and fistulas
- History of Zenker's diverticulum, dysphagia, esophageal stricture, eosinophilic esophagitis, or achalasia
- Women who are pregnant or lactating

Safety and effectiveness of Vibrant in pediatric patients have not been established (1).

Related policies
Amitiza, Ibsrela, Linzess, Motegrity, Opioid Antagonist Drug Class, Trulance

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vibrant may be considered **medically necessary** if the conditions indicated below are met.

Vibrant may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic idiopathic constipation (CIC)

AND ALL of the following:

1. Inadequate treatment response to **ALL** of the following laxative therapies:
    a. Bulk-forming laxative [e.g., psyllium (Metamucil)]
    b. Stimulant laxative [e.g., senna (Senokot)]
    c. Osmotic laxative [e.g., polyethylene glycol 3350 (Miralax)]
2. Inadequate treatment response to another legend constipation medication (see Appendix 1)

3. Absence of gastrointestinal obstruction
4. **NO** dual therapy with other legend constipation medications (see Appendix 1)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Chronic idiopathic constipation (CIC)

AND ALL of the following:
1. Improvement in constipation symptoms
2. Absence of gastrointestinal obstruction
3. **NO** dual therapy with other legend constipation medications (see Appendix 1)

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 60 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
The Vibrant System is an orally administered capsule indicated for the treatment of adults with chronic idiopathic constipation who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month. Patients who have

a history of complicated/obstructive diverticular disease, suspected obstruction in the small intestine or colon, significant gastroparesis, significant gastrointestinal disorder, Zenker's diverticulum, esophageal stricture, eosinophilic esophagitis, achalasia, are pregnant, or lactating. Safety and effectiveness of Vibrant in pediatric patients have not been established (1).

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

References

1. Vibrant website. 2024. Vibrant [online]. Available at: https://www.vibrantgastro.com
2. Vibrant health care provider website. 2024. Vibrant HCP [online]. Available at https://www.vibranthcp.com
3. De Novo Classification Request for Vibrant System. US Food and Drug Administration. 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210052.pdf. Accessed October 8, 2024.

Policy History

Date	Action
June 2023	Addition to PA
September 2023	Annual review
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

Appendix 1 - List of Legend Constipation Medications

Generic Name	Brand Name
linaclotide	Linzess
lubiprostone	Amitiza
methylnaltrexone	Relistor
naldemedine	Symproic
naloxegol	Movantik
plecanatide	Trulance
prucalopride	Motegrity
tenapanor	Ibsrela
Vibrant System	Vibrant System