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| <b>Section:</b>    | Prescription Drugs      | <b>Effective Date:</b>       | October 1, 2023 |
| <b>Subsection:</b> | Gastrointestinal Agents | <b>Original Policy Date:</b> | June 16, 2023   |
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**Last Review Date:** September 8, 2023

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## 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

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- 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)

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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

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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. 2023. Vibrant [online]. Available at: <https://www.vibrantgastro.com>
2. Vibrant health care provider website. 2023. 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](https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210052.pdf). Accessed June 28, 2023.

### Policy History

| Date           | Action         |
|----------------|----------------|
| June 2023      | Addition to PA |
| September 2023 | Annual review  |

### Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.**

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## 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 |