

Ingestible Devices, Medical 344

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Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details [*](#).

Purpose:

This policy addresses the medical necessity of Ingestible Devices.

Description & Definitions:

The Vibrant System (Vibrant Gastro Inc.) is a nonpharmacological treatment for constipation. The capsule shaped device mechanically stimulates the colon. The vibrating capsule is designed to alleviate symptoms of chronic idiopathic constipation (CIC) by inducing a bowel movement through mechanical vibration. It is proposed that these vibrations stimulate the intestinal wall and augment the circadian rhythm of colonic contractions, thereby increasing the number of complete spontaneous bowel movements. This type of nonpharmacologic treatment has been proposed as an alternative second-line treatment for constipation following failure of laxative therapy. The device is contraindicated for use in patients with complicated/obstructive diverticular disease, history of bowel obstructions, significant gastroparesis, any form of inflammatory bowel disease or gastrointestinal malignancy, anal fissures and fistulas, and history of Zenker's Diverticulum, Dysphagia, Esophageal stricture, Eosinophilic Esophagitis, and Achalasia. The Vibrant Capsule is magnetic resonance (MRI) unsafe, and x-rays should confirm that the device is not in use prior to imaging. It is recommended that the device be kept away from pacemakers, defibrillators, nerve stimulators, and other devices affected by proximity to a DC (direct current) magnetic field.

Criteria:

There is insufficient scientific evidence to support the medical necessity of this service as it is not shown to improve health outcomes upon technology review.

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
A9268	Programmer for transient, orally ingested capsule
A9269	Programmable, transient, orally ingested capsule, for use with external programmer, per month

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

Reviewed Dates:

- October: 2024 – no changes references updated

Effective Date: November 2023

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Vibrant System (Vibrant Gastro Inc.) for Treatment of Chronic Idiopathic Constipation. (2024, Jul 10). Retrieved Sep 19, 2024, from Hayes - a symplr company: <https://evidence.hayesinc.com/report/eer.vibrant5797>

Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

SHP, Ingestible, VIBRANT, constipation