Sentara® Health Plans

Medicare

Ingestible Devices

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Effective Date	4/2024
Next Review Date	10/2024
Coverage Policy	Medical 344
Version	1

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:

Ingestible Devices are considered not medically necessary for any indication

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:

Effective Date:

- April 2024

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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Special Notes: *

This medical policy expresses Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

Keywords:

SHP, Ingestible, VIBRANT, constipation