

## Ingestible Devices

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**All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.\*.**

**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
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**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:

Including but not limited to: 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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<https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Capsule%2520for%2520constipation%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%2522%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2>

(2023). Retrieved Sep 19, 2023, from Centers for Medicare and Medicaid Services:

<https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=VIBRANT%2%AE%20System&keywordType=starts&areald=all&docType=NCA,CAL,NC D,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance>

(2023, Jun 27). Retrieved Sep 20, 2023, from MCG: <https://careweb.careguidelines.com/ed27/index.html>

(2023). Retrieved Sep 20, 2023, from InterQual: <https://prod.cue4.com/caas/review/login>

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Cycle. (2023). Retrieved Sep 18, 2023, from Department of Health and Human Services - Centers for Medicare and Medicaid Services: <https://www.cms.gov/files/document/2023-hcpcs-application-summary-biannual-1-2023-non-drug-and-non-biological-items-and-services.pdf>

Vibrant System. (2023, Jan 13). Retrieved Sep 18, 2023, from U.S. Food and Drug Administration: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf22/K223031.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223031.pdf)

Zhu, J., Qian, Y., Pan, J., He, C., & Lan, Y. (2022, May). Efficacy and safety of vibrating capsule for functional constipation (VICONs): A randomised, double-blind, placebo-controlled, multicenter trial. Retrieved Sep 20, 2023, from PubMed: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9062239/>

### Special Notes: \*

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. 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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

### Keywords:

SHP, Ingestible, VIBRANT, constipation