Anthem

Medical Policy

Subject: Ingestible Devices for the Treatment of Constipation
Document #: MED.00143
Status: Reviewed
Publish Date: 01/03/2024
Last Review Date: 11/09/2023

Description/Scope

This document addresses the use of ingestible devices as a nonpharmacological treatment of constipation. The capsule shaped devices mechanically stimulate the colon via vibrations with the goal of triggering a bowel movement. Internal mechanical stimulation has been proposed as an alternative second-line treatment of constipation following failure of laxative therapy.

Note: The non-pharmacological treatment of constipation is also addressed in the following document:

- MED.00125 Biofeedback and Neurofeedback
- MED.00141 High-volume Colonic Irrigation

Position Statement

Investigational and Not Medically Necessary:

Ingestible devices for the treatment of constipation are considered **investigational and not medically necessary**.

Rationale

The Food and Drug Administration (FDA) cleared the Vibrant® Gastro System (Vibrant Gastro Inc., Newton, MA) on August 26, 2022, as a de novo “orally ingested transient device for constipation”. The orally administered capsules are indicated for treatment of chronic idiopathic constipation in adults after failure of at least a 1-month trial of laxative therapy. The efficacy and safety of vibrating capsules in treating chronic constipation has been evaluated in randomized, controlled trials (RCTs).

Zhu and colleagues (2022) conducted a randomised, double-blind, placebo-controlled, multicenter trial to evaluate the safety and efficacy of a vibrating capsule. Individuals with functional constipation were recruited from an outpatient clinic and were randomized to receive vibrating (n=53) or sham (n=53) capsules. Eligible individuals had self- reported symptoms of less than 3 complete spontaneous bowel movements (CSBMs) per week for the past 3 months with onset of symptoms at least 6 months prior to study enrollment. Participants also reported the presence of additional symptoms listed on the Bristol Stool Form Scale during more than 25% of defecations. Following a 2-week run-in period, participants took a capsule every 3 or 4 days for a total of 12 capsules within 6 weeks. Follow-up continued for 4 weeks or until laxatives were used. Responders were defined as having an increase in at least one CSBM per week over their baseline frequency. There was a significant between-group difference in the response rates: vibrating capsule 64% vs. sham treatment 36%; between group difference 28% (95% confidence interval [CI]: 10–45%). There were no significant differences in the proportion of adverse events (AEs) between the groups and there were no cases of capsule retention. Limitations included a shortened treatment period (the recommended treatment regimen is 12 weeks) and no long-term follow-up data.

A phase 3, double-blind, placebo-controlled RCT compared the short-term outcomes of individuals who had received either a vibrating or placebo capsule to treat chronic constipation (Rao, 2023). Participants were randomized to 1 of 3 arms, a placebo group (n=149), and 2 active arms with different programmed vibration times (n=163). Participants received capsules 5 days a week for 8 weeks. The primary efficacy endpoints were either the proportion of participants with an increase of 1 or more CSBM per week, or with an increase of 2 or more CSBMs per week in at least 6 of the 8 weeks of the treatment phase. The percentage of participants who met a primary efficacy endpoint was significantly greater in the active treatment groups compared to the placebo group (39.3% compared to 22.1%, p=0.001, and 22.7% compared to 11.4%, p=0.008, respectively, for each efficacy point). There were no reported serious AEs. The authors note that longer duration studies are needed to evaluate the long-term safety and efficacy of the capsules.

In an open label study, Nelson and associates (2017) examined the effect of vibrating and sham capsules on colonic transit time in individuals with functional constipation. An equal number of individuals were randomized to each group (n=12). Individuals in each group underwent a baseline colonic transit measurement and a second colonic transit measurement during the final week of treatment. There were no significant differences between the groups for the slope of progression of the capsule over 48 hours. The decision to use colonic transit as the primary endpoint is questionable as constipation is not well correlated with delayed colonic transit and the majority of individuals with constipation have normal colonic transit (Bharucha, 2013; Nelson, 2017).

The mechanistic effects of vibrating capsules in chronic idiopathic constipation were evaluated in post hoc analyses of two prospective, adaptive, multicenter, randomized, double-blind, and sham-controlled studies (Rao, 2020). The analyses included individuals who received vibrating (n=133) or sham (n=117) capsules. Participants had self-reported constipation symptoms, between 1 and 3 spontaneous bowel movements per week and symptoms were refractory to osmotic and stimulant laxatives for at least 1 month. The study evaluated CSBM response rates in which a response rate was defined as an increase of at least 1 CSBM/week over baseline. Both studies included a 2-week run-in period and an 8-week treatment period, but the vibration session varied. In one study each capsule was programed to vibrate for a single 2-hour session, in the second study each capsule was programmed to vibrate for two 2- hour sessions. There were no differences in CSBM response rates between the treatment and sham groups in either study.

There is a paucity of evidence to support that ingestible vibrating capsules are a safe and effective treatment of chronic constipation. There is a lack of trial outcomes which show a benefit of active treatment over sham treatments. There are no published studies with long-term follow-up data which demonstrates durable and safe outcomes associated with vibrating ingestible device use over time (Saeed, 2023).

Background/Overview

The reported prevalence of constipation varies greatly depending upon the criteria used and the targeted population, but general consensus estimates prevalence at approximately 8-15% of the population (Palsson, 2020). Prevalence is higher in select

populations, including women, minorities, individuals older than 65 years and individuals in a lower socioeconomic status.

Constipation is classified as either primary or secondary. Primary constipation is frequently defined based upon the Rome IV diagnostic criteria. Primary constipation can be categorized as functional constipation, constipation-predominant irritable bowel syndrome or defecatory disorders. Functional constipation, also known as idiopathic constipation, is primarily defined by the presenting symptoms. Constipation is associated with fewer than 3 stools/week, straining at stool, a feeling of incomplete evacuation, the need for digital assistance to complete a bowel movement, bloating and hard or lumpy stools. The diagnosis of functional constipation requires that the individual have two or more of the above symptoms which affect more than 25% of their bowel movements for at least 6 months with active symptoms for the past 3 months (Bharucha, 2020).

The initial treatment of constipation consists of lifestyle changes such as increasing fiber/fluid intake, increasing activity levels and laxatives. Treatment refractory constipation may be treated with medication, such as secretagogue or prokinetic agents, or with biofeedback therapy. Surgery can be considered if other treatments are ineffective. The appropriate surgical intervention is based upon any pathophysiology present and the risk/benefits acceptable to the affected individual (Bharucha, 2020; Paquette, 2016; Włodarczyk, 2021).

The Vibrant Gastro system is a non-pharmacological, intraluminal “mechanical-pill” therapy marketed as a treatment of chronic constipation. The system is comprised of a multi-use activation pod and a 1-month supply of disposable drug-free capsules. A capsule is placed in the base unit or pod and is programmed with an activation code via an electromagnetic signal. The activation code determines the time span of vibration sessions and strength of vibrations. Following activation, the capsule is taken orally. Capsules can be used 2-5 times per week. Each capsule should take 1 day to pass through the digestive tract before being expelled. Typically, the device will begin vibrating 8 hours following activation to allow the capsule to reach the colon. The ingestible capsules are typically taken at night so stimulation begins in the morning, possibly normalizing the biologic circadian rhythm (Rao, 2020). Capsule progress can be monitored via a smartphone application. Endoscopy would be needed to remove retained capsules.

The Vibrant Gastro system is theorized to work in two ways. The ingestible devices may enhance colonic motility by providing direct mechanical stimulation to the intestinal wall leading to the enhanced movement of stool (Zhu, 2022). There is a theory that the human colon is naturally programmed to empty upon awakening in the morning. This biorhythm may be significantly altered in individuals with chronic severe constipation. Rao and associates (2020) note that individuals with constipation report the most bowel movements occurring in the evening hours compared to individuals without constipation who report daytime bowel movements. With extended, consistent use, ingestible devices are hypothesized to resynchronize the biological clock, leading to the restoration of natural bowel movement biorhythm (Rao, 2020).

Definitions

Bristol Stool Form Scale: An ordinal scale of stool consistency types which range from hardest (type 1) to softest (type 7).

Complete Spontaneous Bowel Movement (CSBM): Bowel movement not induced by rescue medication within the prior 24 hours with a reported sense of complete evacuation.

Chronic constipation: Defecation reported as unsatisfactory with symptoms of infrequent stool and/or difficult stool passage lasting at least the previous 3 months.

Functional constipation: Also known as idiopathic constipation is type of chronic constipation with no physiological abnormalities present.

Rome IV Criteria for Functional Constipation[1]:

Must include 2 or more of the following fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis	
a.	Straining during more than one-fourth (25%) of defecations
b.	Lumpy or hard stools (Bristol stool from scale 1–2) during more than one-fourth (25%) of defecations
c.	Sensation of incomplete evacuation during more than one-fourth (25%) of defecations
d.	Sensation of anorectal obstruction/blockage during more than one-fourth (25%) of defecations
e.	Manual maneuvers to facilitate more than one fourth (25%) of defecations (eg, digital evacuation, support of the pelvic floor)
Loose stools are rarely present without the use of laxatives	
Insufficient criteria for irritable bowel syndrome	

To diagnose functional constipation, presence of 2 from the Rome IV criteria (number a,b) with duration between 3 to 6 months is needed.

[1] Włodarczyk J, Waśniewska A, Fichna J, et al. Current overview on clinical management of chronic constipation. J Clin Med. 2021; 10(8):1738

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS

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

ICD-10 Diagnosis

	All diagnoses, including but not limited to the following:
K59.00-K59.09	Constipation

References

Peer Reviewed Publications:

1. Barberio B, Judge C, Savarino EV, Ford AC. Global prevalence of functional constipation according to the Rome criteria: a systematic review and meta-analysis. Lancet Gastroenterol Hepatol. 2021; 6(8):638-648.
2. Bharucha AE, Lacy BE. Mechanisms, evaluation, and management of chronic constipation. Gastroenterology. 2020; 158(5):1232-1249.e3.
3. Blake MR, Raker JM, Whelan K. Validity and reliability of the Bristol Stool Form Scale in healthy adults and patients with diarrhoea-predominant irritable bowel syndrome. Aliment Pharmacol Ther. 2016; 44(7):693-703.
4. Duboc H, Coffin B, Siproudhis L. Disruption of circadian rhythms and gut motility: An overview of underlying mechanisms and associated pathologies. J Clin Gastroenterol. 2020; 54(5):405-414.
5. Gray JR. What is chronic constipation? Definition and diagnosis. Can J Gastroenterol. 2011; 25 Suppl B(Suppl B):7B-10B.
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7. Palsson OS, Whitehead W, Törnblom H, Sperber AD, Simren M. Prevalence of Rome IV functional bowel disorders among adults in the United States, Canada, and the United Kingdom. Gastroenterology. 2020; 158(5):1262-1273.e3.
8. Rao SSC, Lembo A, Chey WD, et al. Effects of the vibrating capsule on colonic circadian rhythm and bowel symptoms in chronic idiopathic constipation. Neurogastroenterol Motil. 2020; 32(11):e13890.
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10. Ron Y, Halpern Z, Safadi R, et al. Safety and efficacy of the vibrating capsule, an innovative non-pharmacological treatment modality for chronic constipation. Neurogastroenterol Motil. 2015; 27(1):99-104.
11. Saeed A, Abuelazm MT, Abdelnabi M, et al. The efficacy and safety of vibrating capsules for functional constipation: a systematic review and meta-analysis of randomized controlled trials. Curr Med Res Opin. 2023; 39(9):1195-1204.
12. Włodarczyk J, Waśniewska A, Fichna J, et al. Current overview on clinical management of chronic constipation. J Clin Med. 2021; 10(8):1738.
13. Zhu JH, Qian YY, Pan J, et al. Efficacy and safety of vibrating capsule for functional constipation (VICONS): A randomised, double-blind, placebo-controlled, multicenter trial. EClinicalMedicine. 2022; 47:101407.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Gastroenterological Association, Bharucha AE, Dorn SD, Lembo A, Pressman A. American Gastroenterological Association medical position statement on constipation. Gastroenterology. 2013; 144(1):211-217.
2. Paquette IM, Varma M, Ternent C, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Evaluation and Management of Constipation. Dis Colon Rectum. 2016; 59(6):479-492.
3. U.S. Food and Drug Administration 513(f) De Novo classification. Vibrant Ltd. DEN210052. Silver Spring, MD: FDA. August 26, 2022. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210052.pdf. Accessed on September 18, 2023.

Websites for Additional Information

1. American Gastroenterological Association (AGA). Constipation. Available at: https://patient.gastro.org/constipation/. Accessed on September 18, 2023.
2. U.S Department of Health and Human Services. National Institute for Diabetes and Digestive and Kidney Disease. Constipation. Available at: https://www.niddk.nih.gov/health-information/digestive-diseases/constipation. Accessed on September 18, 2023.

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Vibrant Gastro System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
	09/27/2023	Updated Coding section with 10/01/2023 HCPCS changes; added A9268, A9269 replacing NOC code A9999.
New	11/10/2022	MPTAC review. Initial document development.

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