# Medical Coverage Policy | Ingestible Devices for the Treatment of Constipation

**EFFECTIVE DATE:** 10|01|2023
**POLICY LAST REVIEWED:** 07|01|2026

## OVERVIEW
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.

## MEDICAL CRITERIA
Not applicable

## PRIOR AUTHORIZATION
Not applicable

## POLICY STATEMENT
Ingestible devices for the treatment of constipation are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for not medically necessary/not covered benefits/coverage.

## BACKGROUND
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 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 randomized, 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 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 a 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).

Haghbin and colleagues (2024) published a meta-analysis of RCTs assessing the impact of vibrating capsules on individuals with chronic idiopathic constipation. The analysis included three articles comprising four studies with 386 individuals in the vibrating capsule group and 319 in the placebo group. The mean CSBM and the need for rescue medications did not significantly improve between the vibrating capsule group and the placebo group. AEs were reported in all studies and consisted of vibration sensation, abdominal pain/discomfort, musculoskeletal, diarrhea and pharyngitis. There were extensive exclusion criteria, and results may not reflect the general population. There is a paucity of long-term clinical outcome data and further study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## CODING

The following HCPCS code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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

## RELATED POLICIES

None

## PUBLISHED

Provider Update, September 2026
Provider Update, January/December 2025
Provider Update, September 2023

## REFERENCES


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