02.01.83 Orally Ingested Transient Device for Constipation

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:
None

Summary

Description
The Vibrant System is an orally-administered, drug-free, battery-powered capsule that delivers mechanical vibrations to the intestinal wall as it passes through the gastrointestinal tract. It is FDA-cleared for the treatment of adults with chronic idiopathic constipation who are refractory to standard laxative therapy.

Summary of Evidence
For individuals with Chronic Idiopathic Constipation (CIC) who receive an orally ingested transient device, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Meta-analysis findings were mixed, with statistical significant improvements with orally ingestible transient

devices for bowel movement without use of laxatives within the last 48 hours (MD =0.159; 95% CI: 0.095 to 0.223; P<0.001) but not for bowel movement without use of laxatives within the last 48 hours with sense of complete evacuation (MD =0.153; 95% CI: −0.218 to 0.523; P=0.422). There was no significant increase in pooled adverse events (OR =1.431; 95% CI: 0.702 to 2.916; P=0.324) for individuals in the orally ingestible transient device groups. Evidence limitations include heterogeneity in findings due to variation in capsule vibration protocols and a lack of high-quality data supporting quality-of-life and functional capacity improvements and durability of improvements beyond 8 weeks. The evidence is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether the use of an orally ingested transient device improves the net health outcome for individuals with constipation.

PRIOR APPROVAL

Not applicable.

POLICY

The use of an orally ingested transient device for the treatment of constipation is considered **investigational** because the evidence is insufficient to determine the effects of this technology on net health outcomes.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

Chronic Idiopathic Constipation (CIC)

Chronic idiopathic constipation (CIC) is a common functional gastrointestinal disorder characterized by persistent symptoms of difficult, infrequent, or incomplete bowel movements without an identifiable underlying structural, metabolic, or secondary cause. Core symptoms include straining, hard or lumpy stools, sensation of incomplete evacuation, and reduced stool frequency. In a systematic review and meta-analysis (Suares 2011) of 100 population-based studies (n=261,040), the pooled prevalence of CIC was 14% (95% CI: 12-17%) according to self-report, questionnaire, or specific symptom-based criteria. Prevalence may vary based on individual characteristics, with higher prevalence reported in women and older adults. Proposed contributing mechanisms are multifactorial and can include impaired colonic motility, dysfunction in neuromuscular coordination, and altered circadian regulation of bowel activity. CIC

is associated with impaired quality of life, increased healthcare utilization, and significant burden on patients and health systems.

Treatment

Initial Treatment

Initial management of chronic idiopathic constipation (CIC) typically involves conservative measures aimed at improving bowel habits and stool consistency. Recommended first-line approaches include lifestyle modifications such as increased dietary fiber intake, adequate fluid consumption, and regular physical activity. When lifestyle and dietary adjustments alone are insufficient, osmotic or stimulant laxatives may also be used. For more persistent symptoms, clinical re-evaluation is recommended and may indicate escalation to appropriate prescription medications, device-based treatments, or surgical interventions.

Orally Ingested Transient Devices

The Vibrant System is an FDA-cleared vibrating capsule designed to treat chronic idiopathic constipation (CIC) by mechanically stimulating the colon to promote bowel movements. The capsule is activated prior to ingestion and programmed to begin vibrating in the large intestine, approximately 14 hours after swallowing, in timed cycles lasting about two hours. Capsules are taken five days per week and are naturally excreted after passage through the gastrointestinal tract. The starter kit includes single-use capsules, an activation pod, and a mobile eDiary for symptom tracking. Traditional dosing involves once-daily ingestion with scheduled skip days, though alternative regimens and capsule designs are under FDA review.

Regulatory Status

The Vibrant System received 510(k) clearance from the U.S. Food and Drug Administration (FDA) on December 8, 2022 (K232830) for the treatment of adults with chronic idiopathic constipation who have not experienced relief of their bowel symptoms by using laxative therapies at the recommended dosage for at least one month.

RATIONALE

This evidence review was created in October 2025 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through October 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and

conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Clinical Context and Therapy Purpose

The purpose of an orally ingested transient device for constipation is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with constipation.

Interventions

The therapy being considered is an orally ingested transient device, i.e., Vibrant System.

Comparators

The comparator of interest is standard medical management for constipation without use of an orally ingested transient device. This may consist of fiber supplementation, laxatives, or osmotic agents.

Outcomes

The general outcomes of interest are symptoms, change in disease status, and treatment-related morbidity. The main clinical outcome is an increase in voluntary bowel movements.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Multiple systematic reviews have evaluated the net health benefit of orally ingestible transient devices in individuals with CIC (Haghbin 2024, Saeed 2023, Math 2023).

Most recently, Haghbin et al (2024) conducted a systematic review and meta-analysis of RCTs that investigated the net health benefit of orally ingestible transient devices in individuals with CIC. Based on a search of 6 databases (Embase, PubMed/MEDLINE, Cochrane Central, Web of Science, Global Index Medicus, and Google Scholar), 2 independent reviewers included 4 fair- to good-quality RCTs (in 3 publications: Rao 2019, Zhu 2022 Rao 2023), published between 2019 and 2023, and involving 605 total

participants (treatment n=386, placebo n=319). The majority of study participants were female, with a mean age that ranged from 41.3 to 46.8 years old. Meta-analysis findings were mixed, with statistical significant improvements with orally ingestible transient devices for bowel movement without use of laxatives within the last 48 hours (MD =0.159; 95% CI: 0.095 to 0.223; P<0.001) but not for bowel movement without use of laxatives within the last 48 hours with sense of complete evacuation (MD =0.153; 95% CI: −0.218 to 0.523; P=0.422). There was no significant increase in pooled adverse events (OR =1.431; 95% CI: 0.702 to 2.916; P=0.324) for individuals in the orally ingestible transient device groups. Evidence limitations include heterogeneity in findings due to variation in capsule vibration protocols and a lack of high-quality data supporting quality-of-life and functional capacity improvements outcomes and durability of improvements beyond 8 weeks. Additional RCTs are needed to further establish patient selection criteria and to clarify the most effective dose, frequency, and duration of treatment.

A symplr Evolving Evidence Review from August 2025 indicated that this evidence provides minimal support for using the Vibrant System for treatment of chronic idiopathic constipation.

Randomized Controlled Trials (RCTs)

No additional RCTs were identified that were published subsequent to those evaluated in the systematic reviews summarized above (Rao 2019, Zhu 2022 Rao 2023).

Rao et al (2023) published the most recent and largest RCT, which was a multicenter, double-blind, placebo-controlled, 3-arm clinical trial at 95 centers in the United States that enrolled 312 individuals with chronic constipation between April 2019 and July 2021. Study participants were 86% female and their ages ranged from 45.9 years in the placebo group to 47.1 years in the vibrating capsule group. Duration of constipation at baseline was longer in the vibrating capsule group (17.9 versus 14.5 years), which raises questions about the adequacy of the randomization process and how the difference may have modified the observed treatment effect. After 8 weeks, on the primary efficacy end points of an increase of ≥ 1 complete spontaneous bowel movements per week ($CSBM_1$) or ≥ 2 CSBMs per week ($CSBM_2$), greater proportions of individuals using the vibrating capsule achieved both primary efficacy end points (39.3% vs 22.1%, p=.001 for $CSBM_1$; 22.7% vs 11.4%, p=.008 for $CSBM_2$). The rates of any adverse event were not statistically significantly different between the vibrating capsule and placebo groups (27% vs 17.4%). Longer-term studies are still needed to establish the durability of the vibrating capsule's efficacy and safety.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are

informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No practice guidelines or position statements were identified that addressed use of an orally ingested transient device for constipation.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		No specific CPT codes
HCPCS	A9268	Programmer for transient, orally ingested capsule
	A9269	Programable, transient, orally ingested capsule, for use with external programmer, per month
Type of Service	Medicine	
Place of Service	Outpatient	

POLICY HISTORY

Date	Reason	Action
October 2025	New Policy	New Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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