Original Effective Date: 05/31/2023
Current Effective Date: 04/11/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C25205-A

Vibrant (transient device for constipation) NC

PRODUCTS AFFECTED

Vibrant (transient device for constipation capsule), Vibrant Starter Kit (transient device for constipation caps – starter kit)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Chronic idiopathic constipation (CIC)

REQUIRED MEDICAL INFORMATION:
Vibrant vibrating capsule system is considered not medically necessary for all indications, including but not limited to chronic idiopathic constipation, due to limited safety and efficacy data. Safety and efficacy was studied in a single phase 3 double blind, randomized, placebo controlled study in 312 patients over 8 weeks. Safety and efficacy of the Vibrant system for long term use (greater than 8 weeks) has not been evaluated. This coverage policy is subject to change based on research and medical literature, or at the discretion of Molina Healthcare. Molina Healthcare will be continuing to evaluate and update this policy as relevant clinical evidence becomes available to determine whether Vibrant (transient device for constipation) provides impact on long term, chronic health outcomes or patient management.

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
NA

PRESCRIBER REQUIREMENTS:
NA

AGE RESTRICTIONS:
NA

QUANTITY:
NA

PLACE OF ADMINISTRATION:
NA

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Laxatives - Miscellaneous

FDA-APPROVED USES:
Indicated 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Vibrant Gastro, Inc. received de novo clearance from the FDA on August 26, 2022 for Vibrant, as a non-pharmacologic, orally administered, vibrating capsule intended to treat adults with chronic idiopathic constipation who have not experienced relief by using available laxative therapies for at least one month. The system is comprised of a single-use, programmable capsule and a pod, which controls activation of the capsule. FDA concludes that this device should be classified into Class II.

Efficacy and Safety of Vibrant Capsule vs. Placebo for the Treatment of Chronic Idiopathic Constipation (Vibrant) (Rao SSC et al., 2022), ClinicalTrials.gov Identifier: NCT03879239.
The study is a prospective, randomized, multicenter, adaptive design, double blinded, placebo-controlled study, to evaluate the efficacy and safety of Vibrant Capsule vs. placebo in relieving constipation in subjects with Chronic Idiopathic Constipation.

Subjects came for 4 visits: Screening (visit 1), baseline (visit 2), after 4 treatment weeks from baseline (visit 3) and after 8 treatment weeks from baseline (Final visit, visit 4). A total of 8 treatment weeks
Three arms were assessed:

- Vibrant Capsule mode A administered 5 times per week
- Vibrant Capsule mode B administered 5 times per week

- Placebo Capsule administered 5 times per week

The difference between the 2 operating modes is in the vibrating sequence during the capsule's operating time.
Following Interim Analysis one active arm was dropped, and the study continued with 2 arms, placebo and an active arm.

Primary Outcome Measures:

1. CSBM1 & CSBM2 Success Rate [Time Frame: 8 weeks of treatment]
   defined as number of subjects with an increase from the run-in period of at least one weekly Complete Spontaneous Bowel Movement (CSBM) during at least 6 of the 8 weeks of treatment, and CSBM2 success rate, defined as number of subject with an increase from the run-in period of at least two weekly Complete Spontaneous Bowel Movement (CSBM) during at least 6 of the 8 weeks of treatment.
   The study will be deemed successful if either the CSBM1 or the CSBM2 success rate is statistically significantly higher in the active arm that was continued after the interim analysis, than in the placebo arm.
   NOTE:
   - A spontaneous bowel movement (SBM) is defined as a bowel movement that occurs at least 48h after laxative/rescue intake and without digital maneuver.
   - A complete spontaneous bowel movement (CSBM) is defined as a spontaneous bowel movement associated with a feeling of complete evacuation by the subject.

2. Adverse event [Time Frame: up to 11 weeks]
   Safety endpoints include all adverse events related and unrelated to the study treatment in all 3 arms

Secondary Outcome Measures:

1. straining using VAS scale (0-10) for straining where "0" is no straining and "10" is unbearable straining [Time Frame: 8 weeks of treatment]
   Change from baseline in average straining in all 3 arms
2. consistency using the bristol stool scale (1-7) where 1 = Separate hard lumps, like nuts (hard to pass) and 7 = watery, no solid pieces, entirely liquid [Time Frame: 8 weeks of treatment]
   Change from baseline in average stool consistency, using the Bristol Stool Scale in all 3 arms
3. bloating sing VAS scale (0-10) for bloating where 0 = No bloating and 10 = Unbearable bloating [Time Frame: 8 weeks of treatment]
   Change from baseline in average bloating in all 3 arms

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Vibrant are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Vibrant capsules include:

- History of complicated/obstructive diverticular disease
- History of intestinal or colonic obstruction or suspected intestinal obstruction.
- Clinical evidence of current and significant gastroparesis
- History of significant gastrointestinal disorder, including any form of inflammatory bowel disease or gastrointestinal malignancy (celiac disease is accepted if the subject has been treated and is in remission), and/or anal fissures and fistulas.
- History of Zenker's diverticulum, dysphagia, esophageal stricture, eosinophilic esophagitis or achalasia
- Women who are pregnant or lactating

OTHER SPECIAL CONSIDERATIONS:

Preparation Instructions:
Setting up the Pod

1. Connect the USB cable to the AC/DC adaptor and to the pod.
2. Connect the AC/DC adaptor of the Pod to an electricity outlet.
3. Best keep the pod always powered up and ready
4. A short "buzz" is heard and light ring indicator flashes blue for about 40 seconds. Once communication is established, light ring indicator stop flashes and stays On. Now the Pod is ready for use.

Administration Instructions:
Activating the Capsule
1. Remove one capsule from the blister package.
2. Open the pod cover.
3. Verify the light indicator is "ON".
4. Check to ensure absence of foreign matters in the capsule groove prior to use. Place capsule in the designated groove in the center of the pod. Remove your hand and wait.
5. After a few seconds the capsule should vibrate 2 times, a light ring indicator turns green, and a short "buzz" should be heard. Remove the capsule from the Pod. The light ring indicator turns blue. Now the capsule is ready to be swallowed.
6. Immediately swallow the capsule with one full glass of water.
7. Close the pod cover.
8. The capsules are intended to be orally ingested up to 5 times per week, as directed by a physician. The capsule should be taken shortly before going to sleep on 5 out of 7 days of the week according to the following schedule: 3 days on, 1 day off, 2 days on, 1 day off.

Caution: Do not connect the USB cable to any other device (such as a computer) as this may potentially harm the pod.

The capsule should not cause any interference during travel activities such as flying and going through airport security.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Vibrant CAPS
Vibrant Starter Kit KIT

REFERENCES

1. Vibrant Gastro, Inc. Vibrant System, 2023. Accessed on March 8, 2023, and available at: https://www.vibrantgastro.com.

2. Rao SSC et al., Gastroenterology Published: February 20, 2023, https://doi.org/10.1053/j.gastro.2023.02.013.
3. Zhu, Jia-Hui et al., eClinicalMedicine 2022;47: 101407 Published online 25 April 2022. https://doi.org/10.1016/j. eclinm.2022.101407.
4. U.S. Food and Drug Administration. 510(k) Summary. Vibrant System. 2022 August 26. Accessed March 8, 2023. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210052.pdf.
5. ClinicalTrials.gov. Efficacy and Safety of Vibrant Capsule vs. Placebo for the Treatment of Chronic Idiopathic Constipation (Vibrant), ClinicalTrials.gov Identifier: NCT03879239. Last updated: December 20, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT03879239?term=NCT03879239&draw=2&rank=1. Accessed March 2023.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q1 2025
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q1 2024
NEW CRITERIA CREATION	Q2 2023