
Medical Policy



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***Current Policy Effective Date: 7/1/26**
(See policy history boxes for previous effective dates)

Title: Bowel Management Devices

Description

Bowel management devices, such as the Coloplast Peristeen systems, Navina Smart Systems and fecal management systems are used to manage chronic constipation, fecal incontinence, or neurogenic bowel dysfunction by evacuating stool or collecting fecal matter in the lower bowel. They include transanal irrigation systems, which use pumps and catheters, and internal catheters with retention balloons to protect skin integrity. The most serious complication of Transanal irrigation (TAI) is bowel perforation. A recent review article estimated the overall risk of perforation to be in the order of 2 per 1 million procedures. Some of the more commonly reported side effects of TAI include abdominal pain, sweating, chills, dizziness, and a general sense of discomfort.

Medical Policy Statement

Transanal irrigation systems (e.g., Coloplast Peristeen Anal Irrigation systems and Navina Systems) are **established** when criteria are met.

Ingestible vibrating capsule devices (e.g., Vibrant System) for the treatment of constipation are **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

Inclusionary Criteria:

Coloplast Peristeen Anal Irrigation systems and Navina Systems are **established** when ALL the following criteria are met:

- The individual is at least 2 years of age.
- and**
- Diagnosed with one or more of the following conditions:
 - Chronic constipation or fecal incontinence due to neurogenic bowel dysfunction; **or**
 - Chronic constipation due to congenital disorders such as Hirschsprung disease, spina bifida or anorectal malformations **and**
 - An adequate course of conservative medical management (including any combination of dietary modifications, bowel training, laxatives or constipation medications) has been unsuccessful or is contraindicated.

Exclusions:

- Transanal irrigation systems when the above criteria are not met.
- Ingestible vibrating capsule devices (e.g., Vibrant System) for the treatment of constipation

CPT/HCPCS Level II Codes

Established codes:

A4453

A4459

A4479

Other codes (investigational, not medically necessary, etc.):

A9268

A9269

Notes:

- *Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*
- *Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.*

Background

Peristeen Anal Irrigation (PAI) System (Coloplast)

The Peristeen Anal irrigation (PAI; also known as rectal irrigation and trans-anal irrigation) is a method for bowel management. It is used to prevent and treat chronic constipation and fecal incontinence. PAI system consists of a single-use irrigation catheter with a balloon for

retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

Peristeen Plus Transanal Irrigation System (Coloplast)

Peristeen Plus Transanal Irrigation System is the upgraded, next-generation version of the original Peristeen Anal Irrigation system, offering identical, clinically proven efficacy for managing fecal incontinence and constipation, but with enhanced usability. The Peristeen® Plus Transanal Irrigation (TAI) system components include, a control unit with a pump, a water bag (with temperature indicator and screw top), tubes, and straps to securely deliver water for bowel management. It uses either a coated, single-use balloon catheter or a cone catheter for insertion.

Peristeen Plus is an effective alternative to conservative bowel management methods. It can be administered independently or with assistance. Used routinely, daily or every other day, it can help reduce the physical discomfort and worry that fecal incontinence and constipation bring.

Peristeen Plus can be used by a wide range of people with neurogenic bowel dysfunction (NBD), from children to adults. The patient must receive thorough instructions from a qualified healthcare professional before using this product.

Navina Classic System

The Navina Classic System is an FDA-cleared transanal irrigation system, approved under 510(k) notifications (K170487, K190977) for managing chronic constipation, fecal incontinence, and neurogenic bowel in adults and children (ages 2+). Developed by Wellspect, it uses a manual pump to control water instillation for bowel emptying, offering personalized, reliable bowel control.

Navina Smart System

The Wellspect Navina Smart System is an FDA-cleared (510(k) K190977 electronic trans-anal irrigation (TAI) system designed to manage chronic constipation and fecal incontinence by instilling water into the colon. It features an app-connected controller for tracking, adjustable balloon inflation, and water flow settings. The device is intended for adults and children from 2 years of age. It uses software-controlled pumps to inflate a balloon and manage water flow, offering customizable, safe, and precise irrigation for users with limited hand dexterity.

Vibrant System

The Vibrant System received its FDA De Novo authorization 12/1/21. The Vibrant system is a, non-pharmacological, drug-free, and swallowable capsule designed to treat adults with chronic idiopathic constipation (CIC). It uses gentle vibrations to stimulate the colon's nervous system, promoting natural motility. The system includes a programmable, single-use capsule and an activator. The Vibrant System activator refers to as the Vibrant Pod, is a device used to

activate and program the Vibrant Gastro™ capsule. The capsule is taken daily, travels to the colon, and vibrates (16 seconds on, 3 minutes off) for about two hours to stimulate the enteric nervous system, prompting contractions. As they pass through the gastrointestinal tract, the capsules vibrate for four pre-programmed periods of 100 min, 120 min, 100 min, 180 min. It takes about three days for the capsules to pass through the gastrointestinal tract, at which point they are excreted in a bowel movement.¹⁰

Constipation and Fecal Incontinence

Constipation and fecal incontinence (FI) may be the result of either functional or organic disorders. Individuals with neurogenic bowel dysfunction (NBD) are frequently affected by organic constipation and organic FI related to open or closed spina bifida, anorectal malformations or Hirschsprung disease. In approximately 95% of children, no organic cause is found, and these children are diagnosed with functional constipation (FC).

Neurogenic Bowel Dysfunction (NBD)

Neurogenic bowel dysfunction (NBD) is the loss of the ability to control defecation as a result of injury to or deterioration of the nervous system which results in constipation or fecal incontinence. NBD can be caused by a variety of neurological conditions such as spinal cord injury (SCI), Parkinson's disease, multiple sclerosis or other conditions that cause impairment or loss of sphincter control and bowel mobility disorders. In children, NBD is most often related to open or closed spina bifida, anorectal malformations or Hirschsprung disease. Bowel dysfunction can also have numerous other causes, such as injury to the bowel or rectum or constipation caused by delayed or slowed transit of stool in the colon.

Summary of Evidence

For individuals who have neurogenic bowel dysfunction, chronic constipation and/or fecal incontinence, the evidence includes one consensus review, a position paper, one retrospective and cross-sectional study, one prospective study and one literature review. Most of the published peer-reviewed scientific literature investigating the use of TAI is specific to individuals with neurogenic bowel dysfunction (NBD). While some studies are limited by small cohort groups, lack of randomization and short-term outcomes, overall, the literature demonstrates that in individuals with NBD, TAI may result in a reduction of fecal incontinence, decrease in costs associated with urinary tract infections, increased independence and improved Quality of Life (QOL). In addition, TAI provides a non-surgical option in individuals with NBD and chronic constipation when other conservative measures have failed such as dietary and lifestyle advice, routine use of laxatives, enemas, suppositories, or manual evacuation. Evidence of effectiveness in children who did not have NBD (primarily functional constipation) is based on a smaller number of studies as expert opinion and literature reviews. Today, transanal irrigation (TAI) is an accepted treatment in children and adults with bowel dysfunction (BD) who do not respond to conservative and medical treatments. TAI use in adults is well-defined in a stepwise pyramid of care, which can be applied when conservative and medical treatment of bowel dysfunction have failed. Giovanni Mosiello et al, 2017 (Consensus Review of Best Practice of Transanal Irrigation in Children), reported that pediatric patients with either functional or organic bowel dysfunction represent a complex group in

whom management is often difficult and TAI has become a valuable therapeutic alternative that may prevent surgical intervention. However, they concluded that patient selection, dedicated healthcare professionals, thorough training, and careful follow-up are the key to TAI success with a tailored approach to the individual patient considering the different underlying bowel pathologies, presenting symptoms, and personal and family dynamics, to increase efficacy and adherence. There is sufficient evidence to determine that the technology results in an improvement in net health outcome.

For individuals who have chronic constipation who receive ingestible vibrating capsule devices, the evidence includes one systematic review and meta-analysis of randomized controlled trial and one phase three, double-blind, placebo-controlled trial. While early-phase randomized, controlled trials (RCTs) report statistically significant short-term improvements in complete spontaneous bowel movement (CSBM) frequency and patient-reported outcomes compared to placebo, subsequent studies have yielded inconsistent findings, and meta-analyses suggest limited overall benefit. Saeed et al (2023) published a systematic review and meta-analysis of randomized controlled trial on the efficacy and safety of vibrating capsules for functional constipation. but concluded that it is not effective in improving bowel movement in patients with functional constipation. The authors recommended that more large-scale randomized controlled trials are needed to confirm the efficacy and safety of vibrating capsules, determine the most effective dose, frequency, and duration of treatment. Existing evidence is constrained by strict inclusion criteria, short study durations, small sample sizes, and lack of long-term outcome data. At this time, ingestible vibrating devices have not been proven to provide sustained clinical benefit or improve long-term outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a 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 individuals and to 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. The following is a summary of the key literature to date.

Transanal Irrigation Coloplast Peristeen Anal Irrigation

Transanal Irrigation (TAI) is an accepted treatment in children and adults with bowel dysfunction (BD) who do not respond to conservative and medical treatments. TAI use in adults is well-defined in a stepwise pyramid of care, which can be applied when conservative and medical treatment of bowel dysfunction have failed. Giovanni Mosiello et al (2017)³ (Consensus Review of Best Practice of Transanal Irrigation in Children), reported that pediatric patients with either functional or organic bowel dysfunction represent a complex group in whom management is often difficult and TAI has become a valuable therapeutic alternative that may prevent surgical intervention. However, they concluded that patient selection, dedicated healthcare professionals, thorough training, and careful follow-up are the key to TAI

success with a tailored approach to the individual patient considering the different underlying bowel pathologies, presenting symptoms, and personal and family dynamics, to increase efficacy and adherence.

Cicchetti et al (2022) published a literature review about neurogenic bowel dysfunction which occurs in people with central nervous system disease or injury and causes loss of bowel control and severe constipation. A total of 14 records were included to evaluate the benefits in terms of efficacy and safety associated with the adoption of the medical device, Peristeen Plus transanal irrigation (TAI) system for bowel dysfunction management. The study demonstrate improved endpoints related to the severity of fecal incontinence, constipation and intestinal disorders in patients using the device. TAI is considered a safe and more effective method than conventional treatments for reducing fecal incontinence, constipation and improving quality of life. The results of this study confirm the benefits of TAI as a second-line treatment in case of failure of conventional medical therapy in the management of the neurogenic gut.¹⁷

Bazzocchi et al (2024) published a position paper that discusses the use of Transanal Irrigation (TAI) as a treatment for chronic constipation, particularly for patients with refractory chronic constipation secondary to neurological diseases or functional constipation.² The authors aimed to clarify the elements that characterize a TAI procedure and identify which patients with functional constipation and defecation disorders may benefit from this treatment. They also intended to standardize the methodology and devices used for TAI, as current practices vary and are not well-defined. The paper focuses on patients with chronic constipation that have not responded to first and second-line treatments and explores the potential of TAI as a therapeutic aid. The authors concluded that since TAI use may be associated with a small risk of serious complications, proper training of the patient and/or the caregivers, including an explanation of colonic perforation's symptoms and emergency management, is essential before starting the treatment. However, the estimated overall risk of perforation in children is very low. Also, although TAI in adults has been well standardized, clinical practice in children still lacks empirical support, and evidence regarding clinical outcomes among different pathologies is poor. Moreover, a reduction of the success rate during follow-up is sometimes reported. Reasons for this reduced response include inadequate washout before initiating TAI, patient's anxiety, discomfort, and/or pain, and infrequent or inadequate irrigations. Nevertheless, an individual-tailored approach based on clinical score evaluation, diary, anorectal manometry, and volumetric enema, that allows the definition of a personalized frequency and volume of irrigations, is effective in preventing and managing TAI complications and improve TAI's long-term success rate.

Transanal Irrigation Navina System

Baaleman et al (2022) published a retrospective and cross-sectional study including pediatric patients who used a Navina TAI system. The authors retrospectively collected baseline characteristics and data on treatment success at 1- and 6-month follow-up (FU). Treatment success was defined as defecating at least 3 times per week and having less than 1 episode of fecal incontinence per week. They cross-sectionally assessed health-related quality of life (HRQoL), treatment adherence, treatment satisfaction (Treatment Satisfaction Questionnaire for Medication [TSQM]), illness perceptions, medication beliefs, and patient empowerment with validated questionnaires. Thirty-four patients were included (median age at start TAI: 11 years old [range, 6–18]), 32 in the retrospective review, and 26 in the cross-sectional survey (median of 3 years after initiation). Most patients were diagnosed with functional constipation (n = 26;

76%) or a neurogenic bowel disorder ($n = 6$; 18%). Treatment success rates significantly improved at each FU compared with baseline (baseline: 4/25 [16%]; 1-month FU: 12/16 [75%], $P = 0.008$; 6-month FU: 11/18 [61%], $P = 0.016$; cross-sectional FU: 13/26 [50%], $P = 0.008$). HRQoL scores were high (PedsQL median, 73 [IQR, 54–85]). Adherence (defined as Medication Adherence Report Scale [MARS] ≥ 23) was low (36%), whereas TSQM effectiveness scores were high (median, 69 [IQR, 47–86]). The majority of children (61%) reported an increase in independence since TAI treatment. Gothenburg Young Persons Empowerment Scale (GYPES) levels were similar to those reported in children with other chronic conditions.¹³ They concluded that TAI with a Navina system is an effective bowel management system for children with intractable constipation or fecal incontinence.

Emmanuel et al (2021) published an open prospective study on the efficacy of the Navina Smart, an electronic system for transanal irrigation, in neurogenic bowel dysfunction (ClinicalTrials.gov number NCT02979808). Eighty-nine consecutive consenting established Spinal Cord Injury (SCI) individuals (61 male; mean age 48, range 18–77) naïve to TAI treatment were recruited from ten centres in seven countries. Subjects had confirmed neurogenic bladder dysfunction (NBD) of at least moderate severity (NBD score equal to or more than 10). Subjects were taught how to use the device at baseline assisted by the Navina Smart app, and treatment was tailored during phone calls until optimal TAI regime was achieved. The NBD score was measured at baseline and at three months follow up (mean 98 days). Safety analysis was performed on the complete population while per protocol (PP) analysis was performed on 52 subjects. Analysis showed a significant decrease in mean Neurogenic Bowel Dysfunction (NBD) score (17.8 to 10, $p < 0.00001$). In subjects with severe symptoms (defined as NBD score ≥ 14), mean NBD scores decreased (19.4 to 10.9, $p < 0.0001$). The number of individuals with severe symptoms decreased from 41 (79%) subjects at baseline to 16 (31%) at three months follow-up. Device failure accounted for the commonest cause for loss of data. Side effects possibly related to the device developed in 11 subjects (12%). Discontinuation due to failure of therapy to relieve symptoms was reported by 5 subjects (6%).¹⁴ The study concluded that Navina Smart is effective for individuals with NBD, even those with severe symptoms. Whilst there were some device problems, the treatment was generally safe.

Vibrant System

An UpToDate review on "Management of chronic constipation in adults" (Wald, 2026) does not mention the use of ingestible vibrating capsule devices as a treatment option.⁸

Saeed et al (2023) published a systematic review and meta-analysis of randomized controlled trial on the efficacy and safety of vibrating capsules for functional constipation. The authors conducted a literature search in English on electronic databases CENTRAL, PubMed, EMBASE, Scopus, and WOS. They investigated the effects of vibrating capsules (VC) on patients with functional constipation. Three RCTs with a total of 601 patients were included in their analysis. The study's results showed no significant difference between vibrating capsules and placebo in terms of responder rate, change from baseline in complete spontaneous bowel movements (CsBM) and spontaneous bowel movements (SBM), and incidence of adverse events. The specific values included a responder rate of RR 1.37 with 95% CI [0.82, 2.28], $p = .22$, CsBM change from baseline of MD 0.21 with 95% CI [-0.26, 0.69], $p = .38$, SBM change from baseline of MD 0.14 with 95% CI [-0.22, 0.49], $p = .46$, and incidence of adverse events of RR 1.45 with 95% CI [0.79, 2.63], $p = .23$. The authors concluded that vibrating capsules are

safe and well-tolerated, but not effective in improving bowel movement in patients with functional constipation.⁷ They recommended that more large-scale randomized controlled trials are needed to confirm the efficacy and safety of vibrating capsules, determine the most effective dose, frequency, and duration of treatment.

Rao et al (2023) published a Randomized Placebo-Controlled Phase 3 Trial of Vibrating Capsule for Chronic Constipation (Clinical trials.gov, Number: NCT03879239).¹⁵ Individuals were randomized to receive either a vibrating or placebo capsule, once daily, 5 days a week for 8 weeks. The primary efficacy end points were an increase of 1 or more complete spontaneous bowel movements per week (CSBM1 responder) or 2 or more CSBMs per week (CSBM2) from baseline during at least 6 of the 8 weeks. Among 904 patients screened, 312 were enrolled. A greater percentage of patients receiving the vibrating capsule achieved both primary efficacy end points compared with placebo (39.3% vs 22.1%, $P = .001$ for CSBM₁; 22.7% vs 11.4% $P = .008$ for CSBM₂). Significantly greater improvements were seen with the vibrating capsule for the secondary end points of straining, stool consistency, and quality-of-life measures compared with placebo. Adverse events were mild, gastrointestinal in nature, and similar between groups, except that a mild vibrating sensation was reported by 11% of patients in the vibrating capsule group, but none withdrew from the trial. The study shows that the vibrating capsule produced significant improvements in bowel symptoms and QOL in patients with chronic constipation and proved to be safe and was well tolerated. Although the positive findings of this 8-week trial are encouraging, longer-duration studies are required to establish its long term efficacy and safety.

Supplemental Information

American Gastroenterological Association (AGA) Clinical Practice Update on Evaluation and Management of Refractory Constipation:2026¹⁶

Transanal irrigation can be effective, particularly in patients with neurogenic bowel dysfunction, as it reduces stool burden, improves bowel emptying, and enhances quality of life. While sacral nerve stimulation improves symptoms in some patients with fecal incontinence, it did not improve symptoms in Chronic Constipation.

Regulatory Status

Anal Irrigation Systems

Table 1.

Devices	Manufacturer	Date Cleared	510(k) No.	Indication
Peristeen Anal Irrigation (PAI), also known as	Coloplast	6/8/2012	K112860	The PAI System is indicated for use by Children (2 years -< 18 years old), adolescent (12

rectal irrigation and trans-anal irrigation, TAI)				years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.
Peristeen® Plus trans-anal irrigation (TAI)	Coloplast	9/3/2015	K140310	The Peristeen Anal Irrigation System is intended to instill water into the colon through a rectal catheter which incorporates an inflatable balloon inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years - ¹⁸
Classic System	Navina	9/11/2017	K170487	Navina Classic system is indicated for adults who suffer from fecal incontinence, chronic constipation and/or time consuming bowel management. The Navina Classic System is composed of a single use rectal catheter with an inflatable balloon, a water container, a control unit for manual control of instillation water flow and manual balloon inflation and deflation, and tubing with integral connectors for connection of the device components. The Navina Classic System is intended to promote evacuation of the contents of the colon and rectum by instilling water into the lower part of the colon through the rectal catheter which incorporates an inflatable balloon. ⁴

Smart System	Navina	11/22/2019	K190977	The Navina Systems are indicated for use for children (2 - <12 years old), adolescents (12 - <18 years old), and transitional adolescents (18 - <21 years old) patients with neurogenic bowel dysfunction, congenital disorders such as Hirschsprung disease or anorectal malformations, fecal incontinence or chronic constipation where less invasive therapies are not successful, as well as, for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. Use for pediatric patients is to be performed under the supervision of a trained healthcare professional or adult caregiver. By instilling water up into the lower part of the colon, the Navina Systems promote evacuation of the contents of the colon and rectum. The Navina Small Rectal Balloon catheter is limited to use for adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults. The Navina Regular Rectal Balloon catheter is limited to use for adults. The Navina Cone catheter is limited to use for children (2 - < 12 years old), adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults.⁵
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Table 2. Non-Pharmacological Treatment

Devices	Manufacturer	Date Cleared	De Novo	Indication
Vibrant System	Vibrant Ltd.	12/1/2021	DEN210052	The Vibrant System is an orally administered capsule that is 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.⁹ LIMITATIONS Vibrant capsules are contraindicated for use under the following conditions: • 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

Government Regulations**National:****NA****Local:**

L36267 Bowel Management Devices

Original Effective Date

For services performed on or after 12/01/2015

Revision Effective Date

For services performed on or after 04/01/2025

Issue Description

The LCD is revised to update the reference to the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13 to §13.2.3 and 13.5.2. In addition, language regarding noncoverage of fecal collection systems and rectal catheters/tubes used with such systems is revised to make the language clearer. The LCD is also revised to update the long descriptions of HCPCS codes A4453 and A4459, and to remove HCPCS code A4459 from the enema systems language, based on CMS HCPCS coding determinations.

Issue - Explanation of Change Between Proposed LCD and Final LCD

No proposed LCD issued.

CMS National Coverage Policy

National Coverage Determination Manual (Internet-Only Manual 100-03), Chapter 1, Part 4, §230.15, and §280.1.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Benefit Category and other statutory requirements are discussed in the related Policy Article NONMEDICAL NECESSITY AND COVERAGE RULES section. Refer to the Policy article for information on these criteria.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act §1862(a)(1)(A) provisions. In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Bed Pans (E0275, E0276) are covered for beneficiaries who are bed-confined (see NCD 280.1).

Rectal inserts and related accessories (A4337) will be denied as not reasonable and necessary because they do not meet the medical evidence requirements outlined in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13, §13.2.3 and 13.5.2.

Electrical continence aids are in the experimental stage of development and there is no valid scientific documentation of their effectiveness and safety; therefore, they are denied as not reasonable and necessary (see NCD 230.15).

Fecal collection systems and rectal catheters/tubes used with such systems will be denied as statutorily non-covered (no benefit – see related Policy Article).

Enema systems (gravity) coded A4458, will be denied as statutorily non-covered (no benefit – see related Policy Article).

Pulsed irrigation and evacuation systems (E0350, E0352) will be denied as statutorily non-covered (no benefit – see related Policy Article).

Incontinence garments (e.g., briefs, diapers) coded A4520 will be denied as statutorily non-covered (no benefit – see related Policy Article).

Disposable underpads (A4554) and non-disposable (A4553) underpads will be denied as statutorily non-covered (no benefit – see related Policy Article).

Toilet seats, raised toilet seats, toilet seat lift mechanisms, bidets and bidet toilet seats are discussed in the Commodes Local Coverage Determination and related Policy Article.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

Coding Information

Group 1

(13 Codes)

Group 1 Paragraph

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY - No physician or other licensed health care provider order for this item or service
A4453 and A4459 listed in LCD

A54516 Bowel Management Devices-Policy Article

Original Effective Date

10/01/2015

Revision Effective Date

04/01/2025

Article Guidance

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

In order for any item to be eligible for coverage under Medicare, the item must be eligible for inclusion into one of the existing coverage Benefit Categories. Rectal inserts, electrical incontinence aids, and transanal irrigation (TAI) systems (which are comprised of a TAI device and rectal catheter that has a sealing function [balloon or cone-based]) are covered under the Prosthetic Devices benefit (Social Security Act §1861(s)(9)). Bed pans are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary’s equipment to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Many bowel management devices (see bulleted list below, not all inclusive) fail one or more of the relevant requirements in §1861(n) of the Act and are thus statutorily excluded from coverage (see the CMS Nation Coverage Determinations Manual (Internet-only Manual 100-03) Chapter 1, Part 4, §280.1):

- Disposable Sheets and Bags (A4335) – Deny – Non-reusable disposable supplies
- Incontinence Pads (A4553 and A4554) – Deny – Non-reusable supply; Hygienic item
- Diapers (A4520) - Deny – Non-reusable supply; Hygienic item

Gravity-administered enema systems do not meet the Durable Medical Equipment (DME) benefit because these devices do not meet the requirement of durability. In addition, these devices do not meet the Prosthetic Benefit because they do not replace a non-functioning internal body organ.

Fecal collection systems and rectal catheters/tubes used with such systems do not meet the Durable Medical Equipment (DME) benefit because these devices do not meet the requirement of durability. In addition, these devices do not meet the Prosthetic Benefit because they do not replace a non-functioning internal body organ.

Pulsed irrigation and evacuation devices (PIE – P.I.E. Medical Inc., Buford, GA) do not meet the DME benefit because they are considered institutional equipment.

Vaginal inserts and related accessories (Eclipse Vaginal Insert system - Pelvalon, Inc) for the treatment of fecal incontinence are not DME MAC jurisdiction. Claims for vaginal inserts and related accessories (A4563 - RECTAL CONTROL SYSTEM FOR VAGINAL INSERTION, FOR LONG TERM USE, INCLUDES PUMP AND ALL SUPPLIES AND ACCESSORIES, ANY TYPE EACH) submitted to the DME MACs will be rejected as wrong jurisdiction.

CODING GUIDELINES

Rectal inserts are prosthetic devices constructed of rubber, latex, silicone or other similar material and act as a barrier to the passage of fecal matter through the rectum. Use code A4337 (INCONTINENCE SUPPLY, RECTAL INSERT, ANY TYPE, EACH) for this item. Code A4337 includes the insert and any associated supplies or accessories for insertion and maintenance of the device.

An electrical continence aid is a prosthetic device consisting of a plastic plug, molded into the shape of the patient's anal canal, which contains two implanted electrodes that are connected by a wire to a small portable generator. An electrical current is produced which stimulates the

anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

HCPCS code A4458 (ENEMA BAG WITH TUBING, REUSABLE) describes a device used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or simply as a method of bowel management. An enema system consists of an irrigation fluid holding chamber and a rectal catheter (with or without an inflatable balloon). Fluid is instilled via gravity.

The Peristeen transanal irrigation system is a device used to empty the lower bowel and to prevent chronic constipation and fecal incontinence in patients with neurogenic bowel dysfunction. The system consists of a water reservoir, a screw top, a disposable rectal catheter with an inflatable balloon, a control unit, tubing, and a pump.

When billing claims with dates of service on or after January 1, 2015 through March 31, 2025 for the Peristeen transanal irrigation system:

- the correct HCPCS code to bill is A4459,
- HCPCS code A4459 is an all-inclusive code at initial issue,
- separate billing of any of the individual components is not allowed at initial issue, and
- for billing refills of the disposable rectal catheter, HCPCS code A4453 must be used.

When billing claims with dates of service on or after April 1, 2025 for the Peristeen transanal irrigation system:

- the correct HCPCS codes to bill are A4459 and A4453,
- HCPCS code A4459 is **not** an all-inclusive code at initial issue as it does not include the disposable rectal catheter,
- separate billing of the disposable rectal catheter (A4453) is payable at initial issue of the system, and
- for billing refills of the disposable rectal catheter, HCPCS code A4453 must be used.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Fecal Incontinence—Investigational Treatments

References

1. Emmanuel A. Review of the efficacy and safety of transanal irrigation for neurogenic bowel dysfunction. *Spinal Cord*. 2010 Sep;48(9):664-73. doi: 10.1038/sc.2010.5. Epub 2010 Feb 9. PMID: 20142830.
2. G. Bazzocchi et al. Position paper on transanal irrigation in chronic non-organic constipation. *Digestive and Liver Disease* 56 (2024) 770–777
3. Mosiello G, Marshall D, Rolle U, Crétolle C, Santacruz BG, Frischer J, Benninga MA. Consensus Review of Best Practice of Transanal Irrigation in Children. *J Pediatr Gastroenterol Nutr*. 2017 Mar;64(3):343-352. doi: 10.1097/MPG.0000000000001483. PMID: 27977546.

4. Navina Smart System FDA 510K Premarket Notification (K170487) 2017 [510\(k\) Premarket Notification](#) accessed 3/6/26
5. Navina Smart System, Navina Classic System (K1990977) 2019 510(k) Premarket Notification [510\(k\) Premarket Notification](#) accessed 3/6/26
6. Peristeen Anal Irrigation System (K112860) 2015 FDA 510K Premarket Notification [510\(k\) Premarket Notification](#) accessed 3/16/26
7. Saeed A, Abuelazm MT, Abdelnabi M, Elewidi M, Khaled A, Elzahaby A, Mousa A, Abdelazeem B. 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 Sep;39(9):1195-1204. doi: 10.1080/03007995.2023.2243219. Epub 2023 Aug 12. PMID: 37526021.
8. Wald et al. Update to Date. Management of Chronic Constipation in Adults 2026. Management of chronic constipation in adults - UpToDate accessed 3/6/26
9. Vibrant Gastro, Inc. FDA grants marketing authorization for Vibrant, a new first-in-class, drug-free treatment for adults with chronic idiopathic constipation. News Release. Newton Centre, MA: Vibrant Gastro; August 30, 2022. Available at: DEN210052, Vibrant System, Vibrant Ltd [DEN210052, Vibrant System, Vibrant Ltd](#) Accessed 3/16/26
10. Vibrant Gastro, Inc. How Vibrant works [website]. Newton Centre, MA: Vibrant Gastro; 2023. Available at: <https://www.vibranthcp.com>. Accessed 3/16/26
11. L36267 Bowel Management Devices Original Effective Date For services performed on or after 12/01/2015 Revision Effective Date For services performed on or after 04/01/2025 [LCD - Bowel Management Devices \(L36267\)](#) accessed 3/16/26
12. A54516 Bowel Management Devices-Policy Article Original Effective Date 10/01/2015 Revision Effective Date 04/01/2025 [Article - Bowel Management Devices - Policy Article \(A54516\)](#) accessed 3/6/26
13. Baaleman, D., Wegh, C., Hoogveld, M., Benninga, M., *et al.* Transanal Irrigation in Children *Journal of Pediatric Gastroenterology and Nutrition* June 2022 [Transanal Irrigation in Children - Baaleman - 2022 - Journal of Pediatric Gastroenterology and Nutrition - Wiley Online Library](#)
14. Emmanuel A, Kurze I, Krogh K, Ferreira Velasco ME, Christensen P, Del Popolo G, *et al.* (2021) An open prospective study on the efficacy of Navina Smart, an electronic system for transanal irrigation, in neurogenic bowel dysfunction. *PLoS ONE* 16(1): e0245453. <https://doi.org/10.1371/journal.pone.0245453>
15. Satish S.C. Rao, Eamonn M.M. Quigley, William D. Chey, Amol Sharma, Anthony J. Lembo, Randomized Placebo-Controlled Phase 3 Trial of Vibrating Capsule for Chronic Constipation, *Gastroenterology*, Volume 164, Issue 7, 2023, Pages 1202-1210.e6, ISSN 0016-5085, <https://doi.org/10.1053/j.gastro.2023.02.013>. (<https://www.sciencedirect.com/science/article/pii/S001650852300149X>)
16. American Gastroenterological Association (AGA) Clinical Practice Update on Evaluation and Management of Refractory Constipation:2026 Expert Review Staller, Kyle *et al.* *Clinical Gastroenterology and Hepatology*, Volume 24, Issue 2, 296 – 305 [Clinical Gastroenterology and Hepatology - Export Citations](#)
17. Cicchetti A., Fiore, A., Rumi, F., Multidimensional Analysis of Peristeen Plus Medical Device. *International Journal of Technology Assessment in Health Care*; Cambridge vol 38, Iss. S1 Dec 2022: S75-S75 DOI:10.1017/
18. Peristeen Plus anal Irrigation System 2015. [510\(k\) Premarket Notification](#) Accessed 3/16/26

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/26	4/21/26		Joint policy established (jif/no) Vendor Managed: Northwood

Next Review Date: 2nd Qtr, 2027

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BOWEL MANAGEMENT DEVICES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy criteria apply
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.