Peristeen® anal irrigation system

Clinical Policy ID: CCP.1246

Recent review date: 8/2025

Next review date: 12/2026

Policy contains: Fecal incontinence; manual pump enema system; neurogenic bowel dysfunction; transanal/rectal irrigation.

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Coverage policy

The Peristeen® anal irrigation system (Coloplast Corp., Minneapolis, Minnesota) is clinically proven and, therefore, may be medically necessary as part of a bowel management program when all of the following criteria are met (Johns, 2021; National Institute for Health and Care Excellence, 2022; U.S. Food and Drug Administration, 2025):

- The system is used for the management of neurogenic bowel dysfunction.
- The member is age two years or older.
- The member experiences fecal incontinence, chronic constipation, or time-consuming bowel management procedures.
- Initial management involving diet, bowel habit, laxatives, or constipating medications has failed.

Peristeen is clinically proven and, therefore, may be medically necessary for members experiencing symptoms of low anterior resection syndrome (Bordeianou, 2023).

Peristeen is clinically proven and, therefore, may be medically necessary for members up to 21 years of age who have non-neurogenic bowel dysfunction, have failed initial conservative management, and are candidates for surgical intervention (National Institute for Health and Care Excellence, 2022).

Limitations

All other uses of the Peristeen anal irrigation system are investigational/not clinically proven and, therefore, not medically necessary.

Continued approval of the Peristeen anal irrigation system requires medical review every six months to establish compliance and the need for ongoing treatment.

Alternative covered services

- Multifaceted bowel management programs.
- Abdominal massage.
- Dietary manipulation.
- Oral prokinetic/stimulant drugs.
- Oral laxatives.
- Rectal stimulants (suppositories).
- Digital rectal stimulation.
- Biofeedback.
- Behavioral modification.
- Neuromodulation.
- Surgical (e.g., colostomy antegrade colonic enema (Malone procedure), percutaneous endoscopic colostomy, stoma formation, sphincter reconstruction, and sacral nerve stimulation.

Background

Fecal incontinence is a debilitating symptom resulting from many causes that are broadly classified as organic or functional. Organic causes include neurogenic disorders, inflammatory disorders, obstetric trauma, and anorectal anomalies. Functional fecal incontinence encompasses bowel disturbances, most commonly constipation with or without fecal impaction or overflow diarrhea, without evidence of a structural or biochemical explanation (Bharucha, 2015).

For persons with chronic organic causes such as neurogenic bowel dysfunction for whom the goal is pre-emptive, predictable bowel function, an effective bowel management program involves the modulation of stool consistency, promotion of stool transit through the bowel, and effective reflex or mechanical evacuation of stool from the rectum at an appropriate time and place. Emptying the bowel at a chosen time avoids incontinence, and regular emptying reduces the risk of stool impaction.

Initial treatment for fecal incontinence typically involves a bowel management program personalized for the patient using one or more of the following conservative approaches: dietary modifications, medications (laxatives and suppositories), bowel training, pelvic floor exercises, abdominal massage, biofeedback, manual disimpaction, electrostimulation, and transanal irrigation (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). Surgery may be indicated for fecal incontinence refractory to conservative treatment or for colonic pseudo-obstruction. Often, more than one procedure is necessary to develop an effective bowel routine.

Transanal irrigation is a manual pump enema system used to empty the colon of the maximum of fecal matter using regular irrigation and optimized using an inflatable rectal balloon catheter to make the system watertight. The goal of transanal irrigation is to prevent or minimize chronic constipation and fecal incontinence.

Peristeen is a transanal irrigation method that can be administered independently or with assistance (Coloplast Corp., Undated). Peristeen consists of a control unit with a pump, a water bag, and a rectal catheter with a soft balloon secured inside the bowel so both hands are free during the irrigation. The U.S. Food and Drug

Administration (2025) regulates the Peristeen system as a Class 2 device indicated for use in persons ages two years and older with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Findings

Guidelines

Clinical practice guidelines support the use of transanal irrigation, including systems like Peristeen, for managing bowel dysfunction in various patient populations. The Consortium for Spinal Cord Medicine (Johns, 2021), the American Society of Colon and Rectal Surgeons (Bordeianou, 2023), and the National Institute for Health and Care Excellence (2022) all recommend transanal irrigation as an effective treatment option. These guidelines consistently note its efficacy in reducing constipation and fecal incontinence, with success rates of 40% to 73% reported (Johns, 2021). Transanal irrigation has shown particular benefit for patients with neurogenic bowel dysfunction, such as those with spinal cord injuries, as well as individuals with fecal incontinence resulting from low anterior resection syndrome or neurological injuries (Bordeianou, 2023).

The treatment is generally considered a second-line option after conservative management, but before more invasive procedures like stoma surgery. Guidelines highlight improvements in quality of life, dignity, and independence for patients using transanal irrigation (National Institute for Health and Care Excellence, 2022). While some adverse events like abdominal pain and sweating are noted, one guideline also cited evidence of potential long-term cost savings compared to conservative management approaches (Johns, 2021). These recommendations are based on evidence from randomized controlled trials and other studies demonstrating the clinical effectiveness of transanal irrigation in various patient populations.

Evidence review

Current bowel management is largely empirical with a limited research base. In general, the quality of evidence is lower for non-pharmacological approaches than for pharmacological interventions. The evidence supports transanal irrigation as safe and efficacious noninvasive alternative for a number of bowel-related disorders with improvement in quality of life, although it is associated with a high discontinuation rate.

Efficacy in functional constipation in children

Bolia (2024) conducted a systematic review and meta-analysis evaluating the efficacy of transanal irrigation using Peristeen and other devices for children with functional constipation. The review included five studies with a total of 192 participants from the United Kingdom, Netherlands, and Denmark. The median age of participants ranged from seven to 12.2 years. The pooled success rate for transanal irrigation was 62% (95% confidence interval 52% to 71%), with 5.7% of children unable to tolerate the procedure. The most common adverse event reported was pain, experienced by 21.7% of children. At final follow-up, 14% of children were successfully weaned off transanal irrigation. This study provides evidence that transanal irrigation has a moderate success rate for managing functional constipation in children, with a low incidence of adverse events.

A prospective, nonrandomized study involving 78 children aged four to 18 years with bowel dysfunction unresponsive to conventional treatments received transanal irrigation. On multivariable analysis, only laxative use at enrollment was negatively associated with continence and other outcome measures, suggesting that limiting laxative use in this patient population may improve treatment efficacy (Pini Prato, 2024).

Treatment of low anterior resection syndrome

Low anterior resection is currently the standard of care for treating rectal cancer. Symptoms of low anterior resection syndrome can be difficult to treat and debilitating. Transanal irrigation can significantly enhance bowel function and reduce symptom severity in the short term, with patients reporting notable improvements in stool

frequency both during the day and at night. Although the optimal treatment approach must be tailored, transanal irrigation appears to most benefit those with incomplete evacuation, but it is associated with a significant drop-out rate. Rectal perforation is a concern but occurs infrequently, and long-term outcomes are needed (Ansar, 2024; Sharp, 2025; Yu, 2025).

Emile (2023) reviewed seven randomized controlled trials on treatments for low anterior resection syndrome, including two trials that specifically evaluated transanal irrigation. One trial compared transanal irrigation to conservative treatment and found significantly lower low anterior resection syndrome scores at 12 months (22.9 vs. 32.4, *P* = .002). Another trial compared transanal irrigation with posterior tibial nerve stimulation, showing a 61.5% reduction in major symptoms versus 28.6% for the neurostimulation group, and significantly lower scores at six months (12 vs. 30). These findings suggest that transanal irrigation is associated with the best outcomes among reviewed treatments, with follow-up scores ranging from 12 to 22.9 compared to 29.4 to 33.3 for other treatments, indicating its potential effectiveness for low anterior resection syndrome.

Management of neurogenic bowel dysfunction

Boman (2022) conducted an integrative literature review on the effectiveness and feasibility of transanal irrigation for individuals with neurogenic bowel dysfunction. The review incorporated 19 studies with a total of 1,046 participants, demonstrating significant improvements in fecal incontinence (12 studies), constipation (10 studies), and quality of life (eight studies). Time to evacuation significantly decreased in seven studies, and general satisfaction with bowel habits increased in four studies. However, practical problems were noted, with technical issues reported in up to 86% of cases, and catheter expulsion rates ranging from 3% to 48.1%. Adverse effects such as abdominal pain were noted in eight studies, and discontinuation rates ranged from 35% to 55%. This review highlights the need for high-quality research and thorough user education to address feasibility challenge.

Pediatric neurogenic bowel management in spina bifida

de Souza Xavier (2022) reviewed studies on transanal irrigation for managing neurogenic bowel in children with spina bifida, including 23 studies with 483 participants. The review reported significant improvements in fecal incontinence, with success rates ranging from 66% to 90.4%, and improvements in constipation noted in up to 100% of participants. Adherence rates were consistently above 75%, often surpassing 80%. One study observed a reduction in constipation from 85% to 60% and fecal incontinence from 70% to 25% over an 18-month follow-up. Another study found a reduction in diaper use from 88% to 73%. The average time spent on the procedure was less than 30 minutes, with frequency varying from daily to three times a week. The review supports transanal irrigation as a safe and effective method for managing neurogenic bowel, despite variability in evaluation parameters and definitions, and calls for further research to standardize scales and protocols.

Chronic functional constipation in adults

Emmett (2015) performed a systematic review and meta-analysis on transanal irrigation therapy for adult chronic functional constipation, reviewing seven uncontrolled studies involving 254 participants. The review found that approximately 50% of patients experienced a positive response to the therapy, with a pooled response rate of 50.4% (95% confidence interval 44.3% to 56.5%) under a fixed-effect model and 50.9% (95% confidence interval 39.4% to 62.3%) under a random-effects model. Significant heterogeneity (I^2 = 67.1%) and varied methodologies may have influenced outcomes. Adverse events included abdominal cramps or discomfort (33% to 40%), anorectal pain (5% to 25%), anal canal bleeding (1% to 20%), leakage of irrigation fluid (30% to 75%), and rectal catheter expulsion (39%). The review concluded that while transanal irrigation shows promise for chronic functional constipation, further well-designed prospective trials are needed to establish its effectiveness and long-term benefits.

In 2024, we added new or updated guidelines from The Consortium for Spinal Cord Medicine, the American Society of Colon and Rectal Surgeons, and the National Institute for Health and Care Excellence (Bordeianou

2023; Johns, 2021. National Institute for Health and Care Excellence, 2022). We also rewrote the findings section, which included deleting references from prior to 2014 and adding a new systematic review and meta-analysis (Bolia, 2024). We added an indication for members with low anterior resection syndrome as a result of new literature (Bordeianou, 2023; Emile, 2023).

In 2025, we updated the references with no policy changes warranted.

References

On June 16, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “transanal irrigation,” “Peristeen,” “fecal incontinence,” “constipation,” “Fecal Incontinence” (MeSH), “Constipation/prevention and control” (MeSH), and “Constipation/therapy” (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Ansar M, Boddeti S, Noor K, et al. A systematic review of comparative effectiveness of interventions for low anterior resection syndrome: Impacts on bowel function and quality of life. *Cureus*. 2024;16(10):e72772. Doi: 10.7759/cureus.72772.

Bharucha AE, Dunivan G, Goode PS, et al. Epidemiology, pathophysiology, and classification of fecal incontinence: state of the science summary for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) workshop. *Am J Gastroenterol.* 2015;110(1):127-136. Doi: 10.1038/ajg.2014.396.

Bolia R, Goel A, Thapar N. Transanal irrigation in children with functional constipation: A systematic review and meta-analysis. *J Pediatr Gastroenterol Nutr*. 2024;78(5):1108-1115. Doi:10.1002/jpn3.12200.

Boman E, Nylander M, Oja J, Olofsson B. Transanal irrigation for people with neurogenic bowel dysfunction: An integrative literature review. *Gastroenterol Nurs*. 2022;45(4):211-230. Doi: 10.1097/SGA.0000000000000645.

Bordeianou, L., Thorsen, A, Keller, D, et al. The American Society of Colon and Rectal Surgeons clinical practice guidelines for the management of fecal incontinence. *Dis Colon Rectum.* 2023;66(5):647-661. Doi: 10.1097/DCR.0000000000002776.

Coloplast Corp. Product solutions for patients living with bladder and bowel issues. Bowel irrigation system. Peristeen. http://www.coloplast.us/bladder-and-bowel/professional/product-solutions. Undated.

de Souza Xavier T, Duarte LMR, Martins G. Transanal irrigation to manage neurogenic bowel in the pediatric population with spina bifida: A scoping review. *J Pediatr (Rio J)*. 2023;99(4):322-334. Doi: 10.1016/j.ped.2023.02.001.

Emile SH, Garoufalia Z, Barson S, et al. Systematic review and meta-analysis of randomized clinical trials on the treatment of low anterior resection syndrome. *Surgery*. 2023;173(6):1352-1358. Doi: 10.1016/j.surg.2023.02.010.

Emmett CD, Close HJ, Yiannakou Y, Mason JM. Trans-anal irrigation therapy to treat adult chronic functional constipation: Systematic review and meta-analysis. *BMC Gastroentererol*. 2015;15:139. Doi: 10.1186/s12876-015-0354-7.

Johns J, Krogh K, Rodriguez GM, et al. Management of neurogenic bowel dysfunction in adults after spinal cord injury: Clinical practice guideline for health care providers. *Top Spinal Cord Inj Rehabil*. 2021;27(2):75-151. Doi: 10.46292/sci2702-75.

National Institute for Health and Care Excellence. Peristeen Plus transanal irrigation system for managing bowel dysfunction. Medical technologies guidance. Reference number: MTG36. https://www.nice.org.uk/guidance/mtg36. Published February 2018. Updated June 2022.

National Institute of Diabetes and Digestive and Kidney Diseases. Bowel control problems (fecal incontinence). https://www.niddk.nih.gov/health-information/digestive-diseases/bowel-control-problems-fecal-incontinence. Published 2017.

Pini Prato A, Perretti C, Erculiani M, et al. A structured training for trans anal irrigation in pediatric patients improves outcomes and reduce failures: Results of an interventional multicenter prospective study. *J Pediatr Surg*. 2024;59(9):1806-1815. Doi: 10.1016/j.jpedsurg.2023.12.024.

Sharp G, Findlay N, Clark D, Hong J. Systematic review of the management options available for low anterior resection syndrome (LARS). *Tech Coloproctol*. 2025;29(1):58. Doi: 10.1007/s10151-024-03090-3.

U.S. Food and Drug Administration. FDA 510(k) premarket notification database searched using the term “Peristeen”. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Updated June 16, 2025.

Yu M, Liu Y, Li N, et al. Optimal interventions for low anterior resection syndrome: Bayesian network meta-analysis of randomized controlled trials. *Tech Coloproctol*. 2025;29(1):64. Doi: 10.1007/s10151-024-03099-8.

Policy updates

7/2016: initial review date and clinical policy effective date: 8/2016

8/2017: Policy references updated.

8/2018: Policy references updated.

8/2019: Policy references updated. Policy coverage expanded.

8/2020: Policy references updated.

8/2021: Policy references updated.

8/2022: Policy references updated.

8/2023: Policy references updated.

8/2024: Policy references updated. Coverage modified.

8/2025: Policy references updated.