Prior Authorization Review Panel
MCO Policy Submission

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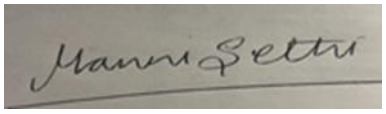
Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices/Keystone First Community HealthChoices	Submission Date: 9/1/2026
Policy Number: CCP.1246	Effective Date: 8/1/2016 Revision Date: 8/1/2026
Policy Name: Peristeen Transanal Irrigation System	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Community HealthChoices

Peristeen Transanal Irrigation System

Clinical Policy ID: CCP.1246

Recent review date: 8/2026

Next review date: 12/2027

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

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The Peristeen transanal 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 (American Gastroenterological Association [Rodriguez, 2026; Staller, 2026]; American Society of Colon and Rectal Surgeons [Bordeianou, 2023]; Consortium for Spinal Cord Medicine [Johns, 2021]):

- The system is used for the management of neurogenic bowel dysfunction or low anterior resection syndrome.
- 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.

Limitations

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

Absolute contraindications to the Peristeen transanal irrigation system include, but are not limited to (Coloplast Corp., undated):

- Known anal or colorectal stenosis
- Colorectal cancer (active/recurrent)
- Radiotherapy to the pelvis
- Recent abdomino-perineal surgery
- Active inflammatory bowel disease
- Current or previous diverticulitis and diverticular abscess
- Chronic symptomatic or complex diverticular disease
- Within three months of abdominal, anal or colorectal surgery
- Within four weeks of endoscopic polypectomy
- Recent colonic biopsy, endoscopic mucosal resection, or endoscopic sub-mucosal dissection
- Severe autonomic dysreflexia
- Ischemic colitis
- During spinal cord shock phase
- In pregnant members who have not used the system before

Continued approval of the Peristeen transanal 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 personalized bowel management program using one or more of the following conservative approaches: dietary modifications, over-the-counter medications (laxatives and suppositories), bowel training, pelvic floor exercises, abdominal massage, biofeedback, manual disimpaction, sacral nerve stimulation, prescription medicines, vaginal balloons, and nonabsorbable bulking agents. 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 (National Institute of Diabetes and Digestive and Kidney Diseases, 2017).

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.

U.S. Food and Drug Administration-cleared transanal irrigation systems include the Peristeen transanal irrigation system (Coloplast Corp., Minneapolis, Minnesota). Peristeen is indicated for patients ages two years and older with neurogenic bowel dysfunction with fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. The Navina Smart System and Navina Classic System (Wellspect HealthCare, a Dentsply Sirona Company, York, Pennsylvania) are indicated for: 1) patients younger than 21 years of age with neurogenic bowel dysfunction, congenital disorders (e.g., Hirschsprung disease), fecal incontinence or chronic constipation where less invasive therapies are not successful, and 2) adults with fecal incontinence, chronic constipation, and/or time-consuming bowel management (U.S. Food and Drug Administration, 2026).

Findings

Guidelines

The Consortium for Spinal Cord Medicine (Johns, 2021), the American Society of Colon and Rectal Surgeons (Bordeianou, 2023), and the American Gastroenterological Association (Rodriguez, 2026; Staller, 2026) all recommend transanal irrigation as an effective non-pharmacologic treatment option for fecal incontinence caused by neurogenic bowel dysfunction and low anterior resection syndrome. The treatment is generally considered a second-line option after failed 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, and the intervention may reduce the need for invasive procedures such as colectomy.

Johns (2021) consistently notes efficacy in reducing constipation and fecal incontinence, reporting success rates of 40% to 73%. Long-term success may be achieved in up to 50% of users (Bordeianou, 2023). Success is typically defined as the proportion of patients continuing transanal irrigation usually because of a perceived benefit, and those who discontinue may pursue other noninvasive interventions such as sacral neuromodulation (Bordeianou, 2023; Rodriguez, 2026).

In children with non-neurogenic functional constipation, neither the American Academy of Pediatrics (Mulhem, 2022) nor the North American Society For Pediatric Gastroenterology, Hepatology & Nutrition (Tabbers, 2014) mentions transanal irrigation as a treatment option.

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 a 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 7 to 12.2 years. The pooled success rate for transanal irrigation was 62% (95% confidence interval 52% to 71%), with 5.7% of participants unable to tolerate the procedure. The most common adverse event reported was pain, experienced by 21.7%. At final follow-up, 14% of participants were successfully weaned off transanal irrigation. There was a low incidence of adverse events.

A prospective, nonrandomized study involving 78 children aged 4 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 debilitating and difficult to treat. Systematic reviews and meta-analyses on effective therapeutic strategies for the condition have produced inconsistent results.

Liu (2025) conducted an umbrella review to synthesize the evidence from published systematic reviews and meta-analyses on transanal irrigation for managing low anterior resection syndrome following sphincter-preserving surgery for rectal cancer. A total of six studies were included, three of which exclusively included randomized controlled trials and conducted meta-analyses. Low to very low quality evidence suggests that transanal irrigation can significantly enhance controlled defecation and quality of life and reduce symptom severity in the short term (≤ six months), with participants reporting notable improvements in stool frequency both during the day and at night. Transanal irrigation appears to benefit those with incomplete evacuation but requires long-term patient adherence. As a prophylactic treatment for low anterior resection syndrome, large-scale, long-term follow-up studies are needed to determine the optimal initiation timing and intervention duration.

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 challenges.

Pediatric neurogenic bowel management in spina bifida

de Souza Xavier (2023) 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

A systematic review of 16 studies enrolled 1,567 adults with chronic constipation unrelated to neurogenic bowel or low anterior resection syndrome. The primary outcome measure was bowel function using patient-reported outcome measures, objective symptom questionnaires, or compliance as a surrogate measure of efficacy. One underpowered randomized trial demonstrated that high-volume transanal irrigation may be more effective than low-volume transanal irrigation. Eight observational studies used a validated bowel-specific patient reported outcome measure, seven of which showed some improvement in quality of life at follow-up. Adverse events were generally mild and most frequently abdominal pain or bloating, anorectal pain, and rectal bleeding. Treatment was discontinued in 3% to 57% of participants across studies (Vollebregt, 2025).

In 2024, we updated the references and rewrote the findings section. We added an indication for members with low anterior resection syndrome as a result of new literature findings.

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

In 2026, we updated the references and modified coverage by deleting the coverage statement for non-neurogenic bowel dysfunction, as this indication does not represent the standard of care in the United States.

References

On June 17, 2026, 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.

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. Peristeen Plus. A better path to bowel control. https://www.coloplast.us/bladder-and-bowel/bowel-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.

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.

Liu T, Jiao X, Hu C, Su R, Dong J, Niu Q. Therapeutic strategies for low anterior resection syndrome: An umbrella review of systematic reviews. *Int J Colorectal Dis*. 2025;40(1):171. Doi: 10.1007/s00384-025-04965-z.

Mulhem E, Khondoker F, Kandiah S. Constipation in children and adolescents: Evaluation and treatment. *Am Fam Physician*. 2022;105(5):469-478. https://www.aafp.org/afp/2022/0500/p469.

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.

Rodriguez L, Ambartsumyan L, Baumgartner K, et al. American Gastroenterological Association-North American Society for Pediatric Gastroenterology, Hepatology and Nutrition pediatric functional constipation clinical care pathway. *Clin Gastroenterol Hepatol*. 2026. Doi: 10.1016/j.cgh.2026.03.003.

Staller K, Neshatian L, Lembo A, Bharucha AE. AGA clinical practice update on evaluation and management of refractory constipation: Expert review. *Clin Gastroenterol Hepatol*. 2026;24(2):296-305. Doi: 10.1016/j.cgh.2025.09.031.

Tabbers MM, DiLorenzo C, Berger MY, et al. Evaluation and treatment of functional constipation in infants and children: Evidence-based recommendations from ESPGHAN and NASPGHAN. *J Pediatr Gastroenterol Nutr*. 2014;58(2):258-74. Doi: 10.1097/MPG.0000000000000266.

U.S. Food and Drug Administration. FDA 510(k) premarket notification database searched using the product code FCE. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Page last updated June 22, 2026.

Vollebregt PF, Baeten CIM, Drewes AM, et al. Transanal irrigation: Bridging the gap in treatment for chronic constipation and/or faecal incontinence-a systematic review and management guidance. *Colorectal Dis*. 2025;27(11):e70274. Doi: 10.1111/codi.70274.

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.

8/2026: Policy references updated. Coverage modified.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1246. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
A4459	Manual transanal irrigation system, includes water reservoir, pump, tubing, and accessories, without catheter, any type