Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania and Keystone First	**Submission Date**: 9/1/2024
Policy Number: ccp.1246	**Effective Date:** 8/2016 **Revision Date:** August 1, 2024
Policy Name: Peristeen® anal irrigation system	

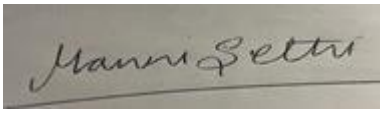
Type of Submission – Check all that apply:

New Policy
X Revised Policy*
Annual Review – No Revisions
Statewide PDL

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

Please provide any clarifying information for the policy below:

See tracked changes below.

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

Keystone First
Family of Health Plans

Peristeen® anal irrigation system

Clinical Policy ID: CCP.1246

Recent review date: 8/2024

Next review date: 12/2025

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

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's 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, 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's 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's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

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 (Dale, 2019; Johns 2021; U.S. Food and Drug Administration, 2023b):

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

Peristeen may also be considered medically necessary for members experiencing symptoms of low anterior resection syndrome (Bordeianou, 2023; Emile, 2023).

Peristeen may be considered medically necessary on a case-by-case basis 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 (Dale, 2019; National Institute for Health and Care Excellence, 2022).

Limitations

All other uses of the Peristeen anal irrigation system are 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.

Current bowel management is largely empirical with a limited research base. In general, the quality of evidence is low for non-pharmacological approaches and high for pharmacological interventions. 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, 2023). 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., 2021). 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 (2023a) 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 from multiple authoritative sources support the use of transanal irrigation, including systems like Peristeen®, for managing bowel dysfunction in various patient populations. The Consortium for Spinal Cord Medicine, the American Society of Colon and Rectal Surgeons, and the National Institute for Health and Care Excellence 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 40-73% 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, the guidelines also cite 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.

Systematic Reviews and Meta Analysis:

Efficacy in Functional Constipation in Children

Bolia, Goel, and Thapar (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 found to be 62% (95% CI: 52-71%), 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 (Bolia, 2024).

Treatment of Low Anterior Resection Syndrome

Emile (2023) reviewed 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=0.002). Another trial compared transanal irrigation with posterior tibial nerve stimulation, showing a 61.5% reduction in major symptoms versus 28.6% for the control, and significantly lower scores at 6 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 (Emile, 2023).

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 (8 studies). Time for evacuation significantly decreased in 7 studies, and general satisfaction with bowel habits increased in 4 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 8 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 (Boman, 2022).

Pediatric Neurogenic Bowel Management in Spina Bifida

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 constipation improvements 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 (Xavier, 2022).

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 patients. The review found that approximately 50% of patients experienced a positive response to the therapy, with a pooled response rate of 50.4% (95% CI: 44.3-56.5%) under a fixed-effect model and 50.9% (95% CI: 39.4-62.3%) under a random-effects model. Significant heterogeneity (I2 = 67.1%) and varied methodologies may have influenced outcomes. Adverse events included abdominal cramps or discomfort (33-40%), anorectal pain (5-25%), anal canal bleeding (1-20%), leakage of irrigation fluid (30-75%), 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 (Emmett, 2015).

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).

References

On May 8, 2023, 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.

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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.