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	**Submission Date**: 9/1/2023
Policy Number: CCP.1246	**Effective Date:** 8/2016 **Revision Date:** August 1, 2023
Policy Name: Peristeen® anal irrigation system	

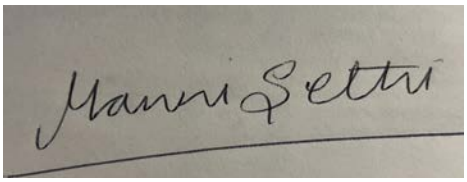
Type of Submission – Check all that apply:

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:

Reinstatement of previously withdrawn policy.

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

Peristeen® anal irrigation system

Clinical Policy ID: CCP.1246

Recent review date: 8/2023

Next review date: 12/2024

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

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania 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 AmeriHealth Caritas Pennsylvania 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. AmeriHealth Caritas Pennsylvania 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. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania 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; 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 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, 2007).

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

We identified two systematic reviews (Coggrave, 2014; Krassioukov, 2010), one cost-effectiveness analysis (Christensen, 2009), and three evidence-based guidelines (National Institute for Health and Care Excellence, 2007; Paquette, 2015; Rao, 2004). Evidence for the Peristeen system consists of one multi-site randomized controlled trial (n = 87 participants) and multiple small, uncontrolled observational studies. Clinical indications in adult populations were for neurogenic bowel dysfunction due to spinal cord injury. In children, causes were neurogenic or anorectal anomalies. All study subjects were unable to achieve reliable bowel continence with other conservative bowel management strategies.

For adults with spinal cord injury, high-quality evidence from one randomized controlled trial suggests overall positive findings for health outcomes using the Peristeen system when conservative bowel management programs fail (Coggrave, 2014; Krassioukov, 2010). Improvements in constipation scores, incontinence, satisfaction scores, and total time for bowel care can be achieved. Patient and caregiver satisfaction was generally high. A survey of 129 participants with bowel dysfunction regarded "risk of fecal incontinence," "frequency of use," and "avoiding urinary tract infections" as the most important features of a transanal irrigation system (Nafees, 2016). There is insufficient evidence to support using Peristeen for any other indication in adults.

Although transanal irrigation may improve health outcomes in some children, the quality of the evidence is very low and patient selection criteria are unclear. Whether the benefits outweigh the risks associated with the procedure cannot be determined. A survey of 18 parents revealed improvement in their child's fecal incontinence, which positively impacted the child's and family's lives despite the need to overcome the emotional difficulty associated with the procedure (Sanders, 2014). The child's physical ability and emotional readiness to develop independent irrigation skills are factors in determining readiness for transanal irrigation.

A study of 70 pediatric patients with fecal incontinence due to a variety of causes (neuro-impairment, Hirschsprungs, anorectal malformation and functional incontinence) submitted to a comprehensive managed protocol using the Peristeen system with fecal scoring, volumetric enema, rectal ultrasound, diary keeping, and anorectal three dimensional manometry. The results demonstrated that transanal irrigations should not be standardized and that 62.9% of the participants required adaptations to the parameters, mainly of irrigated water volume used and number of balloon puffs from the device. Individual tailoring of treatment via manometry increased efficacy (Caruso, 2021).

The overall safety profile from the randomized controlled trial and observational studies of transanal irrigation is acceptable with few and rare adverse effects. An external independent audit of manufacturer data related to the Peristeen system found 49 reports of enema-induced perforation from 2005 to 2013; increased risk was present during treatment initiation and in patients with prior pelvic organ surgery (Christensen, 2016). A search of the U.S. Food and Drug Administration (2023b) Manufacturer and User Facility Device Experience database in 2017 retrieved 49 adverse events associated with the Peristeen system since 2009. Careful patient selection, patient evaluation, and proper training of patients are critical to safe practice of this technique (Christensen, 2016).

Evidence-based guidelines confirmed the overall low-quality evidence supporting non-pharmacological treatment options for fecal incontinence (National Institute for Health and Care Excellence, 2007; Paquette, 2015; Rao, 2004). The National Institute for Health and Care Excellence guideline recommends transanal irrigation as one of a number of options to use, following failure of initial management involving diet, bowel habit, toilet access, medication, and coping strategies. The Institute does not recommend the treatment for the management of idiopathic constipation in children, due to insufficient evidence. Often, more than one procedure is necessary to develop an effective bowel routine as part of a multifaceted, step-wise approach beginning with non-pharmacological, conservative/non-surgical interventions, progressing to pharmacological interventions, and then eventually to surgical interventions. Managing fecal incontinence, particularly related to neurogenic bowel

dysfunction, will likely continue to rely on trial and error until more high-quality studies with larger numbers of participants are conducted (National Institute for Health and Care Excellence, 2007).

In 2017, we found one new cost-effectiveness analysis conducted in the United Kingdom (Emmanuel, 2016) and one retrospective, uncontrolled study (n = 72 participants) (Jorgensen, 2017). In the retrospective study, of the 63 children who fulfilled the Rome III criteria for constipation, 46 (73%) had a complete response and 11 (17%) had a partial response (≥ 50% reduction) to transanal irrigation. Six of nine children with functional non-retentive fecal incontinence showed either a full or partial response to transanal irrigation Transanal irrigation is widely used in children with neurogenic bowel dysfunction but less so in children with functional defecation disorders. Preliminary results from this study suggest transanal irrigation is safe and effective in children with functional fecal incontinence, but the results require confirmation in more rigorously designed studies before widespread use (Jorgensen, 2017).

Transanal irrigation appears cost effective for a heterogeneous population with neurogenic bowel dysfunction who has failed standard bowel care for more than six months based on its ability to reduce episodes of fecal incontinence (36% reduction), urinary tract infections (29% reduction), and stoma surgery (35% reduction), and slightly improve quality-adjusted life years (Emmanuel, 2016).

In 2018, we added no new information, and no policy changes are warranted.

In 2019, we added a new evaluation from the National Institute for Health and Care Excellence (Dale, 2019). The evaluation expanded indications for transanal irrigation to include persons with neurogenic and non-neurogenic bowel dysfunction. They based their policy change on evidence from one randomized controlled trial, 12 observational case series of adults, 11 case series of children, and clinical experience with 111 children of mixed bowel dysfunction etiologies within the National Health Service. Peristeen can reduce the severity of constipation and incontinence, avoid surgical intervention, improve quality of life, and promote dignity and independence, and should be considered an option for people requiring additional treatment strategies to manage bowel dysfunction.

Based on these new findings, we modified the policy to include Peristeen as a medically necessary option for treatment of functional defecation disorders on a case-by-case basis for children up to 21 years of age who have failed initial conservative management and are candidates for surgical intervention.

In 2020, we added two observational studies of transanal irrigation use in children with chronic bowel dysfunction (Lallemant-Dudek, 2020; Patel, 2020). The findings are consistent with previous findings, and no policy changes are warranted.

In 2021, we added one systematic review (Mekhael, 2021) of 27 studies (n = 1,435, only one randomized), the results of which are consistent with the current policy.

In 2022, we added one small study (Caruso); no changes in coverage are warranted.

In 2023, we removed citations of and references to the Centers for Medicare and Medicaid Services, along with language in the coverage section referring to Medicare members only.

We added a systematic review of seven studies (n = 254) of adult chronic functional constipation treated with transanal irrigation; the proportion of subjects with a positive outcome was 50.4% (Emmett, 2015).

We added a systematic review/meta-analysis of seven studies, revealing transanal irrigation reduced symptoms of major low anterior resection syndrome by 61.5% compared with 28.6% after posterior tibial nerve stimulation (Emile, 2023).

We added a scoping review, including 23 studies, of pediatric subjects with spina bifida that found transanal irrigation was a safe and effective way to manage fecal incontinence (de Souza Xavier, 2023).

We added a review of 19 studies of subjects with neurogenic bowel dysfunction, which determined that transanal irrigation can improve difficulties associated with defecation, incontinence episodes, time need to evacuate, general satisfaction with bowel habits, and quality of life (Boman, 2022).

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.