Clinical Policy Title: Peristeen® anal irrigation system

Clinical Policy Number: CCP.1246

Effective Date: August 1, 2016
Initial Review Date: July 20, 2016
Most Recent Review Date: July 3, 2018
Next Review Date: July 2019

Related policies:

CCP.1223 Cecostomy for fecal incontinence
CCP.1168 Injectable bulking agents for fecal incontinence
CCP.1228 Pelvic floor stimulation as treatment for incontinence

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Prestige Health Choice’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. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice considers the use of the Peristeen® Anal Irrigation System (Coloplast Corp., Minneapolis, Minnesota) to be clinically proven and, therefore, medically necessary as part of a bowel management program when all of the following criteria are met (U.S. Food and Drug Administration, 2018a; Paquette, 2015; Coggrave, 2014; Krassioukov, 2010; National Institute for Health and Care Excellence, 2007):

- Used for the management of neurogenic bowel dysfunction.
- Member is age 2 years or older.
- 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.

Limitations:

Policy contains:
- Neurogenic bowel dysfunction.
- Fecal incontinence.
- Transanal/rectal irrigation.
- Manual pump enema system.
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of the Peristeen anal irrigation system are not medically necessary.

For Medicare members only:

Prestige Health Choice considers the use of a manual pump enema system (e.g., Peristeen) not medically necessary. Manual pump enema systems do not meet either the Durable Medical Equipment benefit or the Prosthetic Benefit criteria (Policy article A54516; Local Coverage Determination L36267).

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. By emptying the bowel at a chosen time, incontinence is avoided, 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, 2016). 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., 2016). 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 (2018a) regulates the Peristeen system as a Class 2 device indicated for use in persons ages 2 years and older with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on May 16, 2018. Search terms were: “transanal irrigation,” “Peristeen,” “fecal incontinence,” “constipation,” “Fecal Incontinence” (MeSH), “Constipation/prevention and control” (MeSH), and “Constipation/therapy” (MeSH).

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic
reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

We identified two systematic reviews (Coggrave, 2014; Krassioukov, 2010), one cost-effectiveness analysis (Christensen, 2009), and three evidence-based guideline (Paquette, 2015; National Institute for Health and Care Excellence, 2007; Rao, 2004). Evidence for the Peristeen system consists of one multi-site randomized controlled trial 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. Improvements in constipation scores, incontinence, satisfaction scores, and total time for bowel care can be achieved. Patient and carer 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.

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 Manufacturer and User Facility Device Experience database retrieved 49 adverse events associated with the Peristeen System since 2009 (U.S. Food and Drug Administration, 2017b). 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 (Paquette, 2015; National Institute for Health and Care Excellence, 2007; Rao, 2004). The National Institute for Health and Care Excellence (2007) recommends transanal irrigation as one of a number of options following failure of initial management involving diet, bowel habit, toilet access, medication, and coping strategies; they do not recommend transanal irrigation 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 approaches beginning with non-pharmacological (conservative and non-surgical) interventions, progressing to pharmacological interventions, and then 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.

**Policy updates:**

In 2017, we found one new cost-effectiveness analysis conducted in the United Kingdom (Emmanuel, 2016) and one retrospective, uncontrolled study (Jorgensen, 2017). Transanal irrigation is widely used in children with neurogenic bowel dysfunction but less so in children with functional defecation disorders. Preliminary results from the retrospective 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, urinary tract infections, and stoma surgery, and slightly improve quality-adjusted life years (Emmanuel, 2016).

In 2018, we added no new information, and no policy changes are warranted. The policy number was changed from 08.02.08 to CCP.1246.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Jorgensen (2017)</td>
<td>Key points:</td>
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<td></td>
<td>• A retrospective study of 72 children (mean age 9.2 +/- 2.2 years, 47 males) with</td>
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<td>treatment-resistant functional fecal incontinence.</td>
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<td>• Full response in 46 (73%) of 63 children who fulfilled the Rome III criteria of</td>
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<td>constipation, with complete remission of incontinence episodes; partial response (≥ 50%</td>
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<td>reduction) in 11 (17%) children.</td>
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<td>• Six of nine children with functional non-retentive fecal incontinence showed either a full</td>
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<td></td>
<td>or partial response to transanal irrigation.</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| Emmanuel (2016)                 | No significant difference in the reduction of incontinence episodes between the children with functional constipation (87%) and children with functional non-retentive fecal incontinence (68%) (p = 0.11). No clinical parameters appear predictive of treatment response.                                                                                                                      | • A deterministic Markov decision model using data from 227 patients with neurogenic bowel dysfunction due to spinal cord injury, multiple sclerosis, spina bifida, and cauda equina syndrome from the U.K. perspective.  
• In a 30-year old patient with spinal cord injury and life expectancy of 37 years, transanal irrigation is a cost-effective treatment strategy for patients with neurogenic bowel dysfunction who have failed standard bowel care for more than six months: 36% reduction in FI episodes, a 29% reduction in urinary tract infections, a 35% reduction in likelihood of stoma surgery, a 0.4 improvement in quality-adjusted life years, and a lifetime cost-saving of £21,768 per patient.  
• Results were robust in sensitivity analysis.                                                                 |                                                                                                                                                           |
| Coggrave (2014)                 | Systematic review of 20 randomized controlled trials (RCTs) (902 total patients), including one multi-site RCT (87 total patients) of transanal irrigation versus conservative bowel management in persons with spinal cord injury. Overall quality: High with low risk of bias for transanal irrigation study, low quality for all other studies. Transanal irrigation provided statistically significant benefits compared to the conservative bowel program for: constipation scores, incontinence, satisfaction scores, and total time for bowel care.  
Very limited evidence from individual trials in favor of a bulk-forming laxative (psyllium), an isosmotic macrogol laxative, abdominal massage, electrical stimulation, an anticholinesterase-anticholinergic drug combination (neostigmine-glycopyrrolate) compared to no treatment or controls, and oral carbonated (not tap) water and abdominal massage with lifestyle advice compared to lifestyle advice alone.  
Larger well-designed controlled trials are needed and should include evaluation of the acceptability to patients and effect on their quality of life.                                                                 |                                                                                                                                                           |
| Krassioukov (2010)               | Systematic review of 57 studies, including one RCT and two pre-post studies of Peristeen. Overall quality: High for RCT, moderate for pre-post studies. Evidence showed reduced frequency of lower urinary traction, improved fecal continence, and reduced constipation after 10 weeks of use compared with conservative bowel treatment following Paralyzed Veterans of America Clinical Practice Guidelines for Bowel Management. Positive responses were greatest in the more severely impaired participants who used a wheelchair or were confined to bed (versus ambulatory participants).                                                                 |                                                                                                                                                           |
| Christensen (2009)              |                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                           |
Cost-effectiveness of transanal irrigation versus conservative bowel management for patients with spinal cord injury

- Cost-effectiveness analysis based on results of a previous RCT (Christensen, 2006), cost data, and interview data from the German perspective.
- Transanal irrigation significantly reduced symptoms of neurogenic bowel dysfunction. Product-related costs were higher for transanal irrigation using the self-administered system, but costs associated with carer to help with bowel management, changes/washing due to leakage, urinary tract infections, and patient time spent were reduced.
- The results were robust in the sensitivity analysis.
- The study was supported by Coloplast A/S.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**
Local Coverage Determinations (LCDs):


Commonly submitted codes

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

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<tr>
<td>R15.9</td>
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<td>K59.09</td>
<td>Chronic constipation</td>
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<tbody>
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<td>A4459</td>
<td>Manual pump enema system, includes balloon, catheter and all accessories,</td>
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<tr>
<td></td>
<td>reusable, any type</td>
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