Covered by Vista Health Plan, Inc.

Clinical Policy Title: Peristeen® anal irrigation system

Clinical Policy Number: 08.02.08

Effective Date: August 1, 2016
Initial Review Date: July 20, 2016
Most Recent Review Date: July 20, 2017
Next Review Date: July 2018

Policy contains:
- Neurogenic bowel dysfunction.
- Fecal incontinence.
- Transanal/rectal irrigation.
- Manual pump enema system.

Related policies:
- CP# 08.01.06 Cecostomy for fecal incontinence
- CP# 08.02.04 Injectable bulking agents for fecal incontinence
- CP# 13.02.02 Pelvic floor stimulation as treatment for incontinence

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

Coverage policy

Keystone VIP 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:

- Used for the management of neurogenic bowel dysfunction (NBD).
- Member is age 2 years or older.
- Member suffers from fecal incontinence (FI), chronic constipation, and/or time-consuming bowel management procedures.
- Initial management involving diet, bowel habit, laxatives, or constipiing medications has failed.

Limitations:

All other uses of the Peristeen anal irrigation system are not medically necessary.
For Medicare members only:

Keystone VIP Choice considers the use of a manual pump enema system (e.g., Peristeen) not to be medically necessary. Manual pump enema systems do not meet either the Durable Medical Equipment (DME) benefit or the Prosthetic Benefit criteria.

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

FI 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 FI 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 NBD 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 FI 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 (TAI) (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016). Surgery may be indicated for FI refractory to conservative treatment or for colonic pseudo-obstruction. Often, more than one procedure is necessary to develop an effective bowel routine.

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

Peristeen is a TAI 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 (FDA) 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 FI, chronic constipation, and/or time-consuming bowel management procedures. (FDA, 2017a).

**Searches**

Keystone VIP 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 (CMS).

We conducted searches on June 21, 2017. Search terms were: “transanal irrigation,” “Peristeen,” “fecal incontinence,” and “constipation;” (“Fecal Incontinence/prevention and control”[Mesh] OR "Fecal Incontinence/therapy"[Mesh]) OR ("Constipation/prevention and control"[Mesh] OR "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, one cost-effectiveness analysis, one Hayes Search & Summary report, one evidence-based guideline, and four individual studies not included in the reviews. Evidence for the Peristeen system consists of one multi-site randomized controlled trial (RCT) and multiple small, uncontrolled observational studies. Clinical indications in adult populations were for NBD due to SCI. 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 SCI, high quality evidence from one RCT suggest 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 FI," "frequency of use," and "avoiding urinary tract infections" as the most important features of a TAI system (Nafees, 2016). There is insufficient evidence to support using Peristeen for any other indication in adults.

There is insufficient evidence to support the use of TAI in young children. Although TAI 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 FI, 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 TAI.

The overall safety profile from the RCT and observational studies of TAI 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 FDA Manufacturer and User Facility Device Experience (MAUDE) database retrieved 49 adverse events associated with the Peristeen System since 2009 (FDA, 2016b). 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 FI (National Institute for Health and Clinical Excellence [NICE], 2007; Paquette, 2015; Rao, 2004). NICE recommends TAI as one of a number of options following failure of initial management involving diet, bowel habit, toilet access, medication, and coping strategies; NICE does not recommend TAI for the management of idiopathic constipation in children, due to insufficient evidence (NICE, 2007). Often, more than one procedure is necessary to develop an effective bowel routine. NICE recommends multifaceted, step-wise approaches beginning with non-pharmacological (conservative and non-surgical) interventions, progressing to pharmacological interventions, and then to surgical
interventions. Managing FI, particularly related to NBD, 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 systematic review (Hayes, 2016) that updates their previous report, and one retrospective, uncontrolled study (Jorgensen, 2017). TAI is widely used in children with NBDs but less so in children with functional defecation disorders. Preliminary results from the retrospective study suggest TAI is safe and effective in children with functional fecal incontinence (FFI), but the results require confirmation in more rigorously designed studies before widespread use (Jorgensen, 2017). TAI appears cost-effective for a heterogeneous population with NBD who have failed standard bowel care for more than six months based on its ability to reduce episodes of FI, urinary tract infections (UTIs) and stoma surgery, and slightly improve quality-adjusted life years (QALYs) (Emmanuel, 2016).

A systematic review of Peristeen for bowel management in pediatric populations found low quality evidence from uncontrolled studies that Peristeen is safe and efficacious in the short-term in many groups of children with NBD (Hayes, 2016). However, there is insufficient evidence supporting Peristeen in children with anorectal malformations or Hirschsprung disease. Comparative effectiveness, safety, and long-term effectiveness is unknown. These new findings are consistent with the current policy, and no policy changes are warranted.

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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| Feasibility and efficacy of TAI in FFI | • A retrospective study of 72 children (mean age 9.2 +/- 2.2 years, 47 males) with treatment-resistant FFI.  
• Full response in 46 (73%) of 63 children who fulfilled the Rome III criteria of constipation, with complete remission of incontinence episodes; partial response (≥ 50% reduction) in 11 (17%) children.  
• Six of nine children with functional non-retentive FI showed either a full or partial response to TAI.  
• No significant difference in the reduction of incontinence episodes between the children with FC (87%) and children with FNRFI (68%) (p = 0.11).  
• No clinical parameters appear predictive of treatment response. |
| Emmanuel (2016)        | Key points:                       |
| Long-Term Cost-Effectiveness of TAI in Patients with NBD | • A deterministic Markov decision model using data from 227 patients with NBD due to SCI, multiple sclerosis, spina bifida, and cauda equina syndrome from the U.K. perspective.  
• In a 30-year old patient with SCI and a life expectancy of 37 years, TAI is a cost-effective treatment strategy for patients with NBD who have failed standard bowel care |
<table>
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<tr>
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<tr>
<td>Hayes (2016)</td>
<td>for more than six months: 36% reduction in FI episodes, a 29% reduction in UTIs, a 35% reduction in likelihood of stoma surgery, a 0.4 improvement in QALYs, and a lifetime cost-saving of £21,768 per patient. Results were robust in sensitivity analysis.</td>
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| Peristeen anal irrigation system (Coloplast) for bowel management in pediatric populations | **Key points:**
- Systematic review of nine studies published in eight articles (n=13 to 86 patients) of TAI for bowel management in children with NBD (six studies) or children with anorectal malformations or Hirschsprung disease (three studies).
- Overall quality: very low-to-low with high risk of bias. Small sample sizes, mixed patient populations, lack of a control group in all but one study.
- Peristeen appears efficacious in many groups of children with NBD, and safe in the short-term but unknown in the long-term, although voluntary reports of suspected bowel perforation do not clarify adult from pediatric patients or clinical indication.
- Insufficient evidence in children with anorectal malformations or Hirschsprung disease. Comparative effectiveness, safety, and long-term effectiveness is unknown. |
| Coggrave (2014) | **Key points:**
- Systematic review of 20 RCTs (902 total patients), including one multi-site RCT (87 total patients) of TAI versus conservative bowel management in persons with SCI.
- Overall quality: High with low risk of bias for TAI study, low quality for all other studies.
- TAI 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) | **Key points:**
- 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) | **Key points:**
- Cost-effectiveness analysis based on results of a previous RCT (Christensen, 2006), cost data, and interview data from the German perspective. |
TAI significantly reduced symptoms of NBD. Product-related costs were higher for TAI 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):**

A54516 Bowel Management Devices - Policy Article. CMS website. [https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=54516&ver=15&SearchType=Advanced&CoverageSelection=Both&NCSelection=NC%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&KeyWord=bowel+management&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAAACAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=54516&ver=15&SearchType=Advanced&CoverageSelection=Both&NCSelection=NC%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&KeyWord=bowel+management&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAAACAAAA%3d%3d&). Accessed June 21, 2017.

**Local Coverage Determinations (LCDs):**

L36267 Bowel Management Devices. CMS website. [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36267&ver=17&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&KeyWord=bowel+management&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAAACAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36267&ver=17&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&KeyWord=bowel+management&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=IAAAAACAAAA%3d%3d&).
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.

<table>
<thead>
<tr>
<th>CPT Codes</th>
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<th>Comments</th>
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<tr>
<td>K59.2</td>
<td>Neurogenic bowel</td>
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<tr>
<td>R15.9</td>
<td>Fecal incontinence</td>
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<tr>
<td>K59.09</td>
<td>Chronic constipation</td>
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<thead>
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<th>HCPCS Level II Codes</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>A4459</td>
<td>Manual pump enema system, includes balloon, catheter and all accessories, reusable, any type</td>
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