APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

The Peristeen® Anal Irrigation System is intended to instill water into the colon through a rectal catheter, which incorporates an inflatable balloon, inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. Contraindications: Peristeen Anal Irrigation must not be used in the following situations: known obstruction of the large bowel due to strictures or tumors, acute inflammatory bowel disease, diverticulitis, complex diverticular disease, abdominal or anal surgery within the last 3 months, in patients who are pregnant and have not used the system before (if the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy).¹

Food and Drug Administration²

The Coloplast Peristeen Anal Irrigation (PAI) System (Coloplast A/S) received FDA 510(k) clearance (K083770) on November 23, 2009. According to the approval summary, the Intended Use of the Device is intended to instill water into the colon through a rectal catheter which incorporates an inflatable balloon inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by adolescent (12 years - < 18 years old), transitional adolescent (18 - < 21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. The PAI system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system may be purchased with a carrying case (toilet bag). The rectal catheter is single-use, but the other components may be used multiple times. Accessory kits are available for the components. The PAI System is provided nonsterile and is latex free. It is intended for single patient use only. Two subsequent device clearances have been issued for the Peristeen Anal Irrigation (PAI) System (Coloplast A/S). The Peristeen Anal Irrigation System (Coloplast A/S) received FDA 510(k) clearance (K103254) on January 31, 2011;
another 510(k) clearance (K112860) was issued on June 8, 2012. Both substantially equivalent devices have the same intended use as the predicate device.

**POSITION STATEMENT**

Applicable To:

- Medicaid – Kentucky

The Peristeen Anal Irrigation System (Coloplast) is considered experimental / investigational and not medically necessary due to a lack of established medical efficacy.

**CODING**

Non-Covered HCPCS® Codes
A4459 Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type

Non-Covered ICD-10-CM Diagnosis Codes
K59.00 - K59.09 Constipation, unspecified (K59.00)
K59.2 Neurogenic bowel, not elsewhere classified
R15.9 Full incontinence of feces

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

**REFERENCES**


**MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS**

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>2/7/2019</td>
<td>Approved by MPC. Updated coverage to include Florida Medicaid only; E/I for all other markets.</td>
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<tr>
<td>11/1/2018, 12/7/2017, 10/6/2016</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>10/17/2015</td>
<td>Approved by MPC. New.</td>
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