

## POLICY AND PROCEDURE

<b>POLICY NAME:</b> Peristeen Anal Irrigation System (Coloplast)	<b>POLICY ID:</b> FL.UM.44
<b>BUSINESS UNIT:</b> Sunshine State Health Plan	<b>FUNCTIONAL AREA:</b> Utilization Management
<b>EFFECTIVE DATE:</b> 06/01/2022	<b>PRODUCT(S):</b> Medicaid (MMA), Children's Medical Services (CMS)
<b>REVIEWED/REVISED DATE:</b> 06/22, 05/23	
<b>REGULATOR MOST RECENT APPROVAL DATE(S):</b> N/A	

### POLICY 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.

### PURPOSE:

The Peristeen Anal Irrigation System (Coloplast) **is considered medically necessary** for children under the age of 21 when the Member has tried and failed standard treatment for chronic constipation and impaction (enema or irrigation using standard equipment).

### SCOPE:

Medicaid (MMA), Children's Medical Services (CMS)

This policy applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

### DEFINITIONS:

N/A

### POLICY:

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).

### Food and Drug Administration

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.

# DO NOT FILL

## PROCEDURE:

### Applicable To:

Medicaid – Florida

Children's Medical Services Health Plan (CHIP)

The Peristeen Anal Irrigation System (Coloplast) **is considered medically necessary** for children under the age of 21 when the Member has tried and failed standard treatment for chronic constipation and impaction (enema or irrigation using standard equipment).

## CODING

### HCPCS® Codes

**A4459** Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type

**A9900** Miscellaneous dme supply, accessory, and/or service component of another hcpcs code

### 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

### REFERENCES:

1. Peristeen anal irrigation system. Coloplast Web site. <http://www.coloplast.us>. Accessed January 30, 2020.
2. Peristeen anal irrigation system (Coloplast) for bowel management. Hayes Directory Web site. Published August 13, 2015 (archived November 10 2016).

**ATTACHMENTS:** N/A

**ROLES & RESPONSIBILITIES:** Utilization Management

**REGULATORY REPORTING REQUIREMENTS:** N/A

### REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	Adopted Policy	06/17/2022
Annual Review	Transferred policy to new template Updated Policy ID Updated Footer with fill policy name	06/01/2023

### POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.

SVP Compliance \_\_\_\_\_

Senior Dir. Compliance \_\_\_\_\_