

Clinical Policy: Peristeen® Plus Transanal Irrigation System (Coloplast)

Reference Number: FL.CP.MP.22
Effective Date: 09/26

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The Peristeen® Plus Transanal Irrigation System is intended to decrease the possibility of involuntary bowel leakage or constipation in members with fecal incontinence. The system is designed to instill water into the colon through a rectal catheter, with an inflatable balloon inserted into the rectum to promote evacuation of the lower colon. This policy describes medical necessity requirements for the Peristeen Plus Transanal Irrigation System (Coloplast, Inc.) for Sunshine Health's Managed Medical Assistance (MMA) and Children's Medical Services (CMS) products.

Policy/Criteria

- I. It is the policy of Sunshine Health that the Peristeen Plus Transanal Irrigation System (Coloplast) is **medically necessary** for the following indications:
 - A. Member is ≥ 2 years of age and < 21 years of age, and all of the following:
 1. Member has diagnosis of chronic constipation and impaction;
 2. Member has tried and failed standard treatment for chronic constipation and impaction (e.g., enema or irrigation using standard equipment);
 - B. Member is ≥ 21 years of age with spinal cord injury, and all of the following:
 1. Member has neurogenic bowel dysfunction, one of the following:
 - a. Member suffers from fecal incontinence and/or chronic constipation;
 - b. Member requires time-consuming bowel management procedures.
- II. It is the policy of Sunshine Health that the Peristeen Plus Transanal Irrigation System (Coloplast) is *contraindicated* when the following criteria are met:
 - A. Known obstruction of the large bowel due to strictures or tumors;
 - B. Acute inflammatory bowel disease;
 - C. Diverticulitis;
 - D. Complex diverticular disease;
 - E. Abdominal or anal surgery within the last three months;
 - F. Member is pregnant and has not used the system before (if the member is pregnant and has never used anal irrigation before, the irrigation procedure should not be initiated during pregnancy).

Background

Fecal incontinence describes the involuntary loss of solid or liquid stool often associated with neurogenic bowel dysfunction (NBD). NBD is characterized by constipation and fecal incontinence resulting from impaired central nervous system control of colon function, which may be caused by conditions such as lower limb paralysis, sensory and motor nerve defects in

CLINICAL POLICY

Peristeen Plus Transanal Irrigation System (Coloplast)

the perianal region, or weakened striated muscle function that impairs stool evacuation. The Peristeen® Plus Transanal Irrigation System (formerly known as the Peristeen Anal Irrigation System) is intended to decrease the possibility of involuntary bowel leakage or constipation in members with fecal incontinence.²

The Peristeen Anal Irrigation System has been upgraded to the Peristeen Plus Transanal Irrigation (TAI) System. The updated system is built with the same functionality but now has easier connections, an easier control unit design, and a water temperature indicator, which is especially beneficial to those with reduced hand dexterity. Peristeen Plus with balloon catheter can be used by pediatric (two years of age and older) and adult members with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. With daily or every other day use, TAI can offer an effective bowel emptying method that provides self-confidence, predictability, and peace of mind.¹

Peristeen Plus Transanal Irrigation is contraindicated 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 three months, and in members who are pregnant that have not used the system before (if the member is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy).^{1,2}

Based on a review of full-text clinical practice guidelines and position statements, guidance reflects weak support for the transanal irrigation (TAI) system for bowel management in pediatric populations. The level of support is based on the following:

- Six identified evidence-based guidelines recommended TAI for pediatric populations as part of a stepwise approach to bowel management if conservative treatments have failed.
- One of the 6 guidelines states that Peristeen Plus specifically may offer benefits for children with bowel dysfunction.²

National Institute for Health and Care Excellence (NICE)

The Peristeen transanal irrigation system received a positive recommendation from NICE as an option for people requiring additional treatment strategies to manage bowel dysfunction. Improved patient outcomes are reported in patients who continue to use it with cost likely comparable to standard care.⁵

Food and Drug Administration

The Coloplast Peristeen Anal Irrigation (PAI) System (Coloplast A/S), now named Peristeen Plus Transanal Irrigation System, received FDA 510(k) clearance (K083770) on November 23, 2009. According to the approval summary, the Intended Use of the Device is 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 to < 18 years old), transitional adolescent (18 to < 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

CLINICAL POLICY

Peristeen Plus Transanal Irrigation System (Coloplast)

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. Three 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; and a third 510(k) clearance (K140310) on September 3, 2015. All subsequent clearances have the same intended use as the initial except the 2011 clearance extended use of the device to children at least two years of age.^{3,4}

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPSC Codes	Description
A4459	Manual transanal irrigation system, includes water reservoir, pump, tubing, and accessories, without catheter, any type
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPSC code

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original approval date		06/22
Annual review. No criteria change.		06/23
Transitioned policy to new state specific template and sent to market for approval; policy number changed from FL.UM.44 to FL.CP.MP.22.	07/23	
Annual review. <i>Peristeen Anal Irrigation System</i> changed to <i>Peristeen Plus Transanal Irrigation System</i> throughout policy. Minor rewording with no impact to criteria. Background updated. Codes checked. References reviewed and updated.	09/25	
Annual review. Added clarifying language to description. Updated background. Codes reviewed. HCPSC Code A4459 updated. References reviewed and updated. FL state disclaimer removed from footer.	09/26	

References

1. Coloplast Corporation. Coloplast: Peristeen® Plus: the same Peristeen you know – redesigned to be easier to use! <https://www.coloplast.us/bladder-and-bowel/bowel-solutions/>. Accessed August 3, 2026.
2. Evidence Analysis Research Brief. Peristeen Plus (Coloplast Inc.) for bowel management in pediatric populations. www.hayesinc.com. Hayes. Published May 14, 2024. Accessed August 3, 2026.
3. U.S. Department of Health and Human Services. Food and Drug Administration (FDA). Coloplast: product summary-Peristeen anal irrigation system, irrigation accessory unit. <https://www.accessdata.fda.gov/CDRH510K/K103254.pdf>. Published September 17, 2014. Accessed August 3, 2026.
4. Midrio P, Mosiello G, Ausili E, et al. Peristeen (®) transanal irrigation in paediatric patients with anorectal malformations and spinal cord lesions: a multicentre Italian study. *Colorectal Dis*. 2016;18(1):86 to 93. doi:10.1111/codi.13101
5. Dale M, Morgan H, Carter K, White J, Carolan-Rees G. Peristeen Transanal Irrigation System to Manage Bowel Dysfunction: A NICE Medical Technology Guidance. *Appl Health Econ Health Policy*. 2019;17(1):25-34. doi:10.1007/s40258-018-0447-x

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

CLINICAL POLICY



Peristeen Plus Transanal Irrigation System (Coloplast)

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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