

Medical Policy



Peristeen Anal Irrigation System

Policy Number: PG0413
Last Review: 09/01/2024

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

☒ Professional/DME Provider
☐ Facility

DESCRIPTION:

The Peristeen Anal Irrigation System (Coloplast Corp., Minneapolis, MN) is designed to minimize the likelihood of involuntary bowel leakage or constipation. The system consists of a single-use irrigation catheter that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon, thereby promoting adequate evacuation of the contents of the lower colon. The rectal catheter is non-sterile, intended for single-use, and packaged and labeled accordingly. The other components may be used multiple times.

The water stimulates the bowel and flushes out the stool over approximately 10 to 30 minutes. The device is designed to be used routinely (daily or every other day). The manufacturer suggests that it may take 4 to 12 weeks to establish a regular routine of use. Parameters that may be adjusted for individuals include the volume of water used, the frequency of irrigation, and the amount of air pumped into the balloon.

The Peristeen Anal Irrigation System is a prescriptive device and should only be prescribed by a licensed physician for patients at least two years of age with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. However, substantial questions about comparative effectiveness and safety remain. Although studies reported no serious complications, post-marketing safety data include reports of bowel perforations related to use of the Peristeen system in adults and children.

POLICY:

Paramount Commercial Insurance Plans

- The Peristeen Anal Irrigation System (A4459) is covered as of April 1st, 2022

Elite (Medicare Advantage) Plans

- Manual pump enema systems (e.g., Peristeen anal irrigation system, A4459) are considered not medically necessary and not covered, considered experimental/investigational

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans

Manual pump enema systems (e.g., Peristeen™ Anal Irrigation System) may be considered medically necessary, as part of a bowel management program, for patients diagnosed with neurogenic bowel dysfunction (NBD) when ALL the following criteria are met:

- The member is age 2 years of age or older; AND
- The member suffers from neurogenic bowel dysfunction with fecal incontinence, chronic constipation and/or time-consuming bowel management procedures that significantly impact the individual's quality of life (i.e., inability to participate fully in school or work); AND
- A healthcare provider must prescribe device; AND
- Initial management involving diet, bowel habits, laxatives and constipating medications has failed.

Limitations:

- Manual pump enema systems (e.g., Peristeen™ Anal Irrigation System) is considered experimental, investigational and/or unproven when the above criteria are not met.
- Known anal or colorectal stenosis
- Colorectal cancer, radiotherapy to the pelvis, and recent abdomino-perineal surgery
- Active inflammatory bowel disease, diverticulitis, and ischemic colitis
- Chronic and complex diverticular disease
- Abdominal, anal, or colorectal surgery within the last 3 months
- Within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection, and recent endoscopic sub-mucosal dissection
- Severe autonomic dysreflexia, or during spinal cord shock phase
- In patients who are pregnant and have not used the system before (if the individual is pregnant and has never used anal irrigation before, the individual should not start the irrigation procedure during pregnancy)

Pulsed irrigation enhanced evacuation (e.g., Pulsed Irrigation Evacuation [PIE] device) is considered experimental, investigational and/or unproven for all indications.

Elite (Medicare Advantage) Plans

For Elite (Medicare Advantage) Plan members only in accordance with National Coverage Determination 100.7 and Local Coverage Determination L36267, a manual pump enema system (e.g., Peristeen) is investigational and, therefore, not medically necessary. Manual pump enema systems do not meet either the durable medical equipment benefit or the prosthetic benefit criteria

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES

A4459	Manual pump enema system, includes balloon, catheter and all accessories, reusable, any type
A4453	Rectal catheter for use with the manual pump-operated enema system, replacement only

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 09/22/2017

Date	Explanation & Changes
09/22/17	<ul style="list-style-type: none">• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/28/2020	<ul style="list-style-type: none">• Medical policy placed on the new Paramount Medical policy format
03/25/2022	<ul style="list-style-type: none">• Policy updated to reflect most current clinical evidence• Effective April 1st, 2022, procedure A4459 will be covered for the Commercial product lines

03/02/2023	<ul style="list-style-type: none"> Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/29/2023	<ul style="list-style-type: none"> Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
09/01/2024	<ul style="list-style-type: none"> Medical Policy reviewed and updated to reflect the most current clinical evidence.

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

NCDs <https://www.cms.gov/medicare-coverage-database/searchresults.aspx?keyword=&keywordType=starts&areald=s29&docType=NCD&contractOption=all>

LCDs <https://www.cms.gov/medicare-coverage-database/searchresults.aspx?keyword=&keywordType=starts&areald=s29&docType=F,P&contractOption=all>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/>
Industry Standard Review

Hayes, Inc., Lansdale, PA: Author. Health Technology Assessments. <https://www.hayesinc.com/>

Industry Standard Review