

Medical Policy



Bowel Irrigation/Evacuation System

Description

There are two types of bowel irrigation systems described in this policy- the electronic, pulsed irrigation evacuation system (PIE) and the manual pump-operated enema system (PAI). They are designed to empty the lower bowel, to prevent chronic constipation and fecal incontinence or simply as a method of bowel management. These devices are used to treat chronic constipation and fecal impaction in patients with neurological causes of altered bowel function, including quadriplegia, paraplegia, spinal cord injury, spina bifida, etc., and for bowel preparation for colonoscopy.

Policy Guidelines

Medicare Member Coverage Criteria:

Pulsed irrigation and evacuation systems (E0350, E0352) will be denied as statutorily non-covered because pulsed irrigation and evacuation devices (PIE* – P.I.E. Medical Inc., Buford, GA) do not meet the DME benefit because they are considered institutional equipment.

Enema systems (gravity and manual pump), codes A4458 and A4459 respectively, will be denied as statutorily non-covered because they do not meet the requirement of durability.

Refer to Medicare’s medical policy (L36267) and article (A54516) for coverage criteria.

Non-Medicare Member Coverage Criteria:

Pulsed Irrigation Evacuation (PIE - E0350) of fecal impaction may be considered reasonable and necessary when the following medical criteria is met:

- a. Chronic home use of a device for pulsed irrigation maybe reasonable and necessary for members with neuropathic bowel who have failed conservative techniques of bowel retraining (e.g., suppositories, digital stimulation, abdominal massage, enemas) as evidenced by repeated episodes of impaction requiring practitioner intervention or hospitalization.

PIE is excluded when any of the following contraindications exist:

- a. Abdominal surgeries in the past 12 months.
- b. Renal insufficiency

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- c. Acute diverticulitis
- d. Impactions not in the colon, i.e., ileus.
- e. Integrity of the colon is suspect (suspected perforation).

The **manual**, pump-operated enema system (e.g., Peristeen Anal Irrigation or PAI A4459) may be considered medically necessary as part of a bowel management program when the following criteria are met:

- a. The system is used for the management of chronic neurogenic bowel dysfunction.
- b. It must be prescribed by the treating practitioner.
- c. The member is age 2 years or older.
- d. The member suffers from fecal incontinence, chronic constipation, or time-consuming bowel management procedures that significantly impact the individual's quality of life (i.e., inability to participate fully in work or school).
- e. Other conservative bowel management alternatives must have been tried and been proven ineffective.

HCPCS code A4459 is an all-inclusive code at initial issue. Separate billing of any of the individual components is not allowed at initial issue. For billing refills of the disposable rectal catheter, HCPCS code A4453 (RECTAL CATHETER FOR USE WITH THE MANUAL PUMP-OPERATED ENEMA SYSTEM, REPLACEMENT ONLY) must be used.

PAI is contraindicated in the following scenarios:

- a. Known anal or colorectal stenosis.
- b. Colorectal cancer, radiotherapy to the pelvis, and recent abdominoperineal surgery
- c. Active inflammatory bowel disease, diverticulitis and ischemic colitis
- d. Chronic and complex diverticular disease
- e. Abdominal, anal or colorectal surgery within the last 3 months
- f. Within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection and recent endoscopic sub-mucosal dissection
- g. Severe autonomic dysreflexia, or during spinal cord shock phase
- h. 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)

HCPCS Level II Codes and Description

A4453 Rectal catheter for use with the manual pump operated enema system, **replacement only.**

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A4458	Reusable enema bag
A4459	Manual pump operated enema system, includes balloon, catheter and all accessories, reusable, any type, each.
E0350	Control unit for electronic bowel irrigation/evacuation system
E0352	Disposable pack (water reservoir bag, speculum, valving mechanism and collection bag/box) for use with the electronic bowel irrigation/evacuation system.

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating practitioner in connection with diagnosis and treatment decisions.

Northwood follows all CMS national Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

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References

1. TRICARE, Humana: Pulsed Irrigation Evacuation (PIE) Use of pulsed irrigation evacuation in the management of the neuropathic bowel. 2007; 8: 2.7
2. National Government Services, Inc. Jurisdiction B DME MAC, Bowel Management Devices. Local Coverage Determination No. L36267. Last accessed/reviewed November 6, 2023.
3. Medicare: NGS Jurisdiction B Correct Coding and Coverage memo dated Feb 12, 2015 stating The Peristeen Transanal irrigation system (A4459) is a device used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or simply as a method of bowel management. There is no Medicare benefit for this device; therefore, claims for code A4459 will be denied as noncovered.
4. Minnesota Department of Human Services Medical Supply Coverage Guide, https://mn.gov/dhs/assets/medical-supply-coverage-guide_tcm1053-293319.pdf Accessed and reviewed November 23, 2021, 11/4/2022.
5. Husky Health of Connecticut, Peristeen Anal Irrigation System, https://www.huskyhealthct.org/providers/provider_postings/policies_procedures/Peristeen_Policy.pdf Last accessed and reviewed November 6, 2023.

Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:	Effective Date:
A	11-20-08	Initial Release	Rosanne Brugnoli	Ken Fasse	n/a	
01		Annual Review – no changes	Susan Glomb	Ken Fasse	12-2008	
02	12-22-09	Annual Review- No changes	Susan Glomb	Ken Fasse	Dec.2009	
03	12-	Annual Review –	Susan Glomb	Ken Fasse	Dec.2010	

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	01-10	No changes				
04	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		
05	12-13-11	Annual Review. Changes made to reflect current clinical guidelines of experimental and investigational. References added to policy.	Susan Glomb	Dr. B. Almasri	Dec. 2011	
06	04-03-12	Added reference to NH Medicaid	Susan Glomb	Dr. B. Almasri		
07	08-15-12	Changed to reflect current practice. Added new reference – TRICARE.	Susan Glomb	Dr. B. Almasri	August 2012	
08	11-28-12	Annual review – no changes.	Susan Glomb	Dr. B. Almasri	Nov. 2012	
09	12-30-13	Annual review. No changes	Susan Glomb	Dr. B. Almasri		
10	11-25-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
11	11-16-15	Annual Review. Annual Review. Added Peristeen Transanal Irrigation System as a non covered item A4459 unless covered per state guidelines.	Lisa Wojno	Dr. B. Almasri	November 2015	
12	12-01-	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016	

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	16					
13	12-12-17	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2017	
14	12-01-18	Annual Review. Updated policy to reflect non-coverage for Medicare members. Added Bowel Management Medicare reference.	Lisa Wojno	Dr. C. Lerchin	December 2018	
15	12-06-19	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
16	11-18-20	Annual Review. Changed 'physician' to 'practitioner'.	Lisa Wojno	Dr. C. Lerchin	November 2020	
17	11-29-21	Annual Review. Removed the word "Electronic" from policy title. Added NCD/LCD verbiage to "Important Note". Added references.	Carol Dimech/ Susan Glomb	Dr. C. Lerchin	November 2021	
18	4-1-22	Added guidelines for HCPCS code A4459 manual pump-operated system.	Carol Dimech/Tracy A.	Dr. C. Lerchin	4-1-22	
19	11-4-22	Annual Review. Revised replacement guidelines for code A4453.	Carol Dimech	Dr. C. Lerchin	11-4-22	11-4-22
20	11-6-23	Annual Review. No Changes.	Carol Dimech	Dr. C. Lerchin	11-6-23	11-6-23