



PROVIDER POLICIES & PROCEDURES

PERISTEEN® ANAL IRRIGATION SYSTEM

The primary purpose of this policy is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for the Peristeen Anal Irrigation System (Coloplast, Minneapolis, MN). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

The Peristeen Anal Irrigation (PAI) system, also known as rectal irrigation and trans-anal irrigation, is a method for bowel management. It is used to prevent chronic constipation and fecal incontinence. PAI can be administered either on one's own or with assistance. The PAI system includes a control unit with a pump, a water bag, a rectal catheter, tubing and straps.

CLINICAL GUIDELINE

Coverage guidelines for the PAI system are made in accordance with the CT Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

The PAI system may be considered medically necessary as part of a bowel management program when the following criteria are met:

1. The system is used for the management of chronic neurogenic bowel dysfunction;
2. The individual is age 2 years or older;
3. The individual suffers from 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 work or school);
4. Initial management involving diet, bowel habit, laxatives or constipating medications have failed;
5. The individual has no known contraindications (see below); and
6. For reauthorizations requests only, there is documentation in the physician notes that:
 1. The individual is consistently using the system as directed by their physician; and
 2. The system has shown to be effective in managing fecal incontinence and/or chronic constipation.

PAI is contraindicated in the following scenarios:

- Known anal or colorectal stenosis
- Colorectal cancer, radiotherapy to the pelvis, and recent abdomino-perineal surgery
- Active inflammatory bowel disease, diverticulitis and ischemic colitis

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

1

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

- 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)

Note: since the list of contraindications provided by the manufacturer is not exhaustive, providers should consider individual patient factors when deciding if use of the device is appropriate in a given circumstance.

EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of the PAI system is required. Requests for coverage will be reviewed in accordance with the processes in place for reviewing requests for medical supplies. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

If determined to be medically necessary:

- The initial authorization and first reauthorization will be given for a period of three months. The PAI system will be authorized along with a three month supply of catheters (HCPCS code A4453 – 6 units [15 catheters per unit]).
- Subsequent reauthorizations will be given for a period of one year. The PAI system will be authorized along with a 1 year supply of catheters (HCPCS code A4453 – 24 units [15 catheters per unit]).

Initial Authorization Requests

The following information is needed to review initial authorization requests for the PAI system:

1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. Documentation from the referring provider which supports the medical necessity of the requested item including:
 - a. Other methods of bowel management that have been tried without success (e.g. oral laxatives, suppositories, enemas etc.);
 - b. Any medical complications resulting from chronic fecal incontinence/constipation (e.g. urinary tract infections, hospitalizations, etc.); and
3. Pricing information - Manufacturer's suggested retail price (MSRP) and actual acquisition cost (AAC)* which includes all manufacturer and volume discounts.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

*Ref: DSS Pricing Policy for MEDS items available at:
https://www.huskyhealthct.org/providers/policies_procedures.html#

Reauthorization Requests

The following information is needed to review reauthorization requests for the PAI system:

1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. Documentation from the referring provider that shows ongoing and consistent use of the system and evidence that the system continues to be effective in managing fecal incontinence and/or chronic constipation.
3. Pricing information - Manufacturer's suggested retail price (MSRP) and actual acquisition cost (AAC)* which includes all manufacturer and volume discounts.

*Ref: DSS Pricing Policy for MEDS items available at:
https://www.huskyhealthct.org/providers/policies_procedures.html#

EFFECTIVE DATE

This Policy is effective for prior authorization requests for the PAI system for individuals covered under the HUSKY Health Program beginning August 1, 2019.

LIMITATIONS

N/A

CODES

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

DEFINITIONS

1. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

Benefit programs, collectively.

6. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

Government Agency, Medical Society and Other Publications:

1. Coloplast Corp. Product overview. Bowel irrigation system. Peristeen® anal irrigation system. Available at: <https://www.coloplast.us/peristeen-anal-irrigation-system-en-us.aspx>. Accessed on May 13, 2019.
2. FDA 510(k) Premarket Notification database searched using the term "Peristeen". U.S. Food and Drug Administration website: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
3. FDA MAUDE – Manufacturer and User Facility Device Experience database searched using "Peristeen" for all years. U.S. Food and Drug Administration website: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/textSearch.cfm>

Peer Reviewed Publications

1. Del Popolo G, Mosiello G, Pilati C, et al. Treatment of neurogenic bowel dysfunction using transanal irrigation: A multicenter Italian study. *Spinal Cord*. 2008;46(7):517-522.
2. Christensen P, Andreasen J, Ehlers L. Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients. *Spinal Cord*. 2009;47(2):138-143.
3. Neel KF. Total endoscopic and anal irrigation management approach to noncompliant neuropathic bladder in children: A good alternative. *J Urol*. 2010;184(1):315-318.
4. Rosen H, Robert-Yap J, Tentschert G, et al. Transanal irrigation improves quality of life in patients with low anterior resection syndrome. *Colorectal Dis*. 2011;13(10):e335-e338.
5. Corbett P, Denny A, Dick K, et al. Peristeen integrated transanal irrigation system successfully treats faecal incontinence in children. *J Pediatr Urol*. 2014;10(2):219-222.
6. Alenezi H, Alhazmi H, Trbay M, et al. Peristeen anal irrigation as a substitute for the MACE procedure

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

4

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

in children who are in need of reconstructive bladder surgery. *Can Urol Assoc J.* 2014;8(1-2):E12-E15.

7. Pacilli M, Pallot D, Andrews A, et al. Use of Peristeen® transanal colonic irrigation for bowel management in children: A single-center experience. *J Pediatr Surg.* 2014;49(2):269-272; discussion 272.
8. 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):86-93.

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication		Reviewed and approved at the May 22, 2019 Medical Reviewer meeting. Reviewed and approved by the CHNCT Clinical Quality Subcommittee on June 19, 2019. Approved by DSS on June 24, 2019.
Update	June 2020	Added statement addressing contraindications for treatment. Change approved at the April 8, 2020 Medical Reviewer meeting. Changed approved by the CHNCT Clinical Quality Subcommittee on June 15, 2020. Approved by DSS on June 19, 2020.
Review	March 2021	Reviewed and approved without changes at the March 10, 2021 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 15, 2021. Approved by DSS on March 22, 2021.
Update	March 2022	Updated HCPCS coding. Added HCPCS code A4453. Deleted HCPCS code A9999. Change approved at the March 9, 2022 CHNCT Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on March 21, 2022. Approved by DSS on March 24, 2022.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.