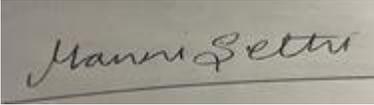


**Prior Authorization Review Panel
MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	Submission Date: 4/1/2024
Policy Number: ccp.1223	Effective Date: 6/2016 Revision Date: March 1, 2024
Policy Name: Cecostomy for fecal incontinence	
Type of Submission – Check all that apply: New Policy <input checked="" type="checkbox"/> Revised Policy* Annual Review – No Revisions Statewide PDL	
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below: Now requires Prior Authorization. See tracked changes below.	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Cecostomy for fecal incontinence

Clinical Policy ID: CCP.1223

Recent review date: 2/2024

Next review date: 6/2025

Policy contains: Chronic constipation; fecal incontinence; open and percutaneous cecostomy.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

Cecostomy is clinically proven and, therefore, may be medically necessary for fecal incontinence when all of the following criteria are met (Assmann 2022; [Bharucha](#), 2017; Itkin, 2011; Liliana, 2023; Paquette, 2015):

- Members age four years or older.
- Members unresponsive to conservative treatment for relieving the bowels for at least a 60-day period. Conservative treatment consists of at least two of the following:
 - Biofeedback.
 - Lifestyle and dietary modifications.
 - Bowel habit interventions.
 - Anal plugs.
 - Pelvic floor muscle training.
 - Rectal irrigation.
 - Drug therapy.
 - Electrostimulation.
- For the purpose of either:
 - Facilitating an antegrade continence enema in members with fecal incontinence secondary to neurologic disease.
 - Providing cecal decompression for members with chronic refractory constipation, chronic colonic pseudo-obstruction, or colonic obstruction.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

All other uses of cecostomy for fecal incontinence are not medically necessary.

Absolute contraindications to cecostomy include previous abdominal surgical procedures; active peritonitis, colitis, or ileocolitis; uncorrectable coagulopathy; bowel ischemia; and excessive abdominal wall fat.

Relative contraindications include recent gastrointestinal bleeding, hemodynamic instability, ascites, respiratory compromise, and certain anatomic alterations.

For members receiving anticoagulant or antiplatelet therapy (Itkin, 2011):

- International Normalized Ratio should be less than 1.5.
- Platelet count should be greater than 50,000/ μ L

Alternative covered services

- Bowel habit interventions.
- Anal plugs.
- Pelvic floor muscle training.
- Rectal irrigation.
- Drug therapy (e.g., bulk-forming agents [fibers], emollient stool softeners, rapidly acting lubricants, prokinetics, laxatives, osmotic agents, and prosecretory drugs).
- Electrostimulation.
- Other surgical or minimally invasive procedures (e.g., colostomy, artificial bowel sphincter, or dynamic graciloplasty).

Background

Fecal incontinence is a debilitating symptom resulting from deficits in factors that control bowel function. Organic causes include neurogenic disorders, inflammatory disorders, obstetric trauma, and anorectal anomalies. Functional causes encompass bowel disturbances, most commonly constipation with or without fecal impaction or overflow diarrhea, without evidence of a structural or biochemical explanation (Bharucha, 2015).

Definitions of fecal incontinence vary according to target population (adults versus children), symptoms, symptom duration, and criteria used (Bharucha, 2015; Paquette, 2015). A working definition from the American Society of Colon and Rectal Surgeons encompasses several factors: "The uncontrolled passage of feces or gas over at least one month's duration, in an individual of at least four years of age, who had previously achieved control" (Paquette, 2015).

Fecal incontinence is a clinical diagnosis primarily based on history and examination, and may include anal manometry, anal ultrasound, colonic transit study, magnetic resonance imaging, defecography, flexible sigmoidoscopy or colonoscopy, and anal electromyography (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). Initial treatment typically involves one or more of the following conservative approaches: dietary modifications, medications (laxatives and suppositories), rectal irrigation, bowel training, pelvic floor exercises, biofeedback, manual disimpaction, and electrostimulation. Surgery may be indicated for fecal incontinence refractory to conservative treatment or for colonic pseudo-obstruction.

Cecostomy is the creation of an opening in the cecum to facilitate an antegrade continence enema or to provide cecal decompression (Itkin, 2011). The procedure involves a standard colonoscopy preparation followed by placement of a temporary decompressive or lavage cecostomy tube (C-tube) surgically or percutaneously with endoscopic or image guidance. Fluoroscopically-guided percutaneous cecostomy is performed according to the

technique first described by Chait, et al. (1997) in treating fecal incontinence in children (see also Itkin, 2011). The cecostomy tube/catheter used in this procedure has received marketing approval as a Class II device (U.S. Food and Drug Administration, 2021).

For open cecostomy, the hospital length of stay ranges from five to 10 days. Patients undergoing percutaneous cecostomy typically have a shorter hospital stay. Approximately one week after the procedure, the patient begins self-administering antegrade continence enemas through the C-tube, and an individualized irrigation routine is established. After six weeks, the temporary catheter is exchanged for a semipermanent, low-profile cecostomy catheter designed to accommodate different lengths of subcutaneous tissue. This exchange is an outpatient procedure performed by a gastroenterologist, colorectal surgeon, or interventional radiologist over a wire with fluoroscopic guidance, without sedation or antibiotic coverage. Replacement of the semipermanent catheters is performed annually.

Findings

We identified three systematic reviews or evidence reports, four evidence-based guidelines, two new case series, one retrospective cohort study, and no economic studies for this policy. The evidence consists of largely single-institution, retrospective case series without comparators.

The American Gastroenterological Association and the Society of Interventional Radiology in joint guidelines suggest several pre-procedural measures for cecostomy, applicable based on patient risk. For low-risk conditions, recommendations include stopping warfarin five days prior and ensuring International Normalized Ratio is below 1.5, alongside managing clopidogrel and aspirin therapies. High-risk patients should also cease warfarin five days before, substitute it with low molecular weight heparin, and carefully manage clopidogrel and aspirin. Additionally, the Society recommends correcting International Normalized Ratio above 1.5, ensuring adequate platelets, withholding clopidogrel for five days, continuing aspirin, and managing low molecular weight heparin doses appropriately before the procedure (Itkin, 2011). American Gastroenterological Association released updated guidelines in 2017, but no policy changes are warranted ([Bharucha, 2017](#)).

An American Academy of Family Physicians guideline for treating constipation in the elderly does not mention cecostomy as an option (Mounsey, 2015).

In 2022, the United European Gastroenterology, European Society of Coloproctology, European Society of Neurogastroenterology and Motility and the European Society for Primary Care Gastroenterology issued diagnosis and treatment of fecal Incontinence that mirrors others published (Assmann, 2022).

The American Society of Colon and Rectal Surgeons' 2023 guidelines reviewed 182 sources on fecal incontinence, highlighting cecostomy in 2 case series with a total of $n = 134$ adults. At 22-48 months follow-up, 78-100% of patients continued using antegrade enemas via cecostomy tubes. Additionally, a retrospective study ($n = 75$) showed a decrease in mean Wexner scores from 14.3 to 3.4 post-treatment. Despite limited evidence, cecostomy tubes are considered for highly motivated patients with refractory fecal incontinence, aiming to avoid permanent fecal diversion (Liliana, 2023).

A systematic review of 40 studies ($n = 2,086$) of pediatric fecal incontinence showed the complication rate after cecostomy was lower compared to after appendicostomy (16.6% versus 42.3%). The most frequent complication after appendicostomy was stenosis, occurring in 16.7% of patients. Leakage was the second most common complication after appendicostomy at 10.8%. In contrast, stenosis and leakage were rare after cecostomy, occurring in only 0.5% and 2.3% of patients, respectively. Revision of surgery owing to failure was required in

1.5% of cecostomy patients compared to 16.5% of appendicostomy patients. Only 0.5% of cecostomy patients required a diverting ostomy due to failure, versus 3.0% of appendicostomy patients. Achievement of fecal continence and improvement in patient quality of life were similar in both groups, but need for surgical revision was 15% higher after appendicostomy (Mohamed, 2020).

A systematic review/meta-analysis of three studies (n = 166) compared Malone appendicostomy and cecostomy tube insertion among children with intractable constipation. No significant difference existed in the percent achieving continence (80% to 70%). Need for additional surgery was higher in Malone appendicostomy patients (30% versus 12%, $P = .01$) (Li, 2018). Complication rates also varied between the two procedures. No significant difference was found in fecal leakage around the insertion site between the two methods, although there was high heterogeneity across studies. The Malone appendicostomy group had a higher rate of infection at the insertion site (18%) compared to the cecostomy group (10%), with a relative risk of 2.59 (95% confidence interval: 1.08 to 6.16). Additionally, excessive granulation tissue was notably higher in patients treated with cecostomy tube insertion (49%) compared to Malone appendicostomy (13%), with a relative risk of 0.35 (95% confidence interval: 0.13 to 0.97).

A systematic review of 45 articles (n = 1157) of pediatric idiopathic constipation included only two which were randomized, many with small sample sizes (median = 16). Half of the studies had heterogeneous populations, and follow-up was short (median 1.5 years). Antegrade continence enema operation-open/laparoscopic assisted, cecostomy, was successful in 82% of cases, with high morbidity and reoperations. Colon resection and pull-through operations reported good outcomes in 79% of children but were also associated with significant morbidity and a 10% reoperation rate. Botulinum toxin injections and internal sphincter myectomy were comparably effective in the short term. A permanent colostomy was successful in 86% of refractory cases (Siminas, 2015).

In a study of 290 children with fecal incontinence, the success rate of cecostomy placement was 98%, and 92% had a successful exchange to a low-profile tube. In addition, 29% experienced one or more early problems after cecostomy, and 3% had major complications (Khan, 2015).

One Cochrane review found a striking lack of high-quality randomized controlled trials on fecal incontinence surgery, with existing trials focusing on sacral neuromodulation and injectable bulking agents (Brown, 2013). Therefore, clinical research provides limited guidance for use of alternative surgical procedures such as cecostomy.

A review observes that surgery for bowel obstruction has high recurrence, elevated morbidity and mortality, comorbidities that may prevent surgical intervention, and limits of endoscopic stent placement. Decompressive cecostomy placement is minimally invasive, safe, and effective, and more data will better define its indications (Miller, 2017).

References

On January 4, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “cecostomy” [MeSH] and free text terms

“cecostomy” and “caecostomy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Assmann SL, Keszthelyi D, Kleijnen J, et al. Guideline for the diagnosis and treatment of fecal incontinence-A UEG/ESCP/ESNM/ESPCG collaboration. *United European Gastroenterol J.* 2022;10(3):251-286.

Doi:10.1002/ueg2.12213

Bharucha AE, Rao SSC, Shin AS. Surgical Interventions and the Use of Device-Aided Therapy for the Treatment of Fecal Incontinence and Defecatory Disorders. *Clin Gastroenterol Hepatol.* 2017;15(12):1844-1854. Doi:10.1016/j.cgh.2017.08.023

Bharucha AE, Dunivan G, Goode PS, et al. Epidemiology, pathophysiology, and classification of fecal incontinence: State of the science summary for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) workshop. *Am J Gastroenterol.* 2015;110(1):127-136. Doi: 10.1038/ajg.2014.396.

Bordeianou LG, Thorsen AJ, Keller DS et al. The American Society of Colon and Rectal Surgeons clinical practice guidelines for the management of fecal incontinence. *Dis Colon Rectum.* 2023;1;66(5):647-661. Doi: 10.1097/DCR.0000000000002776.

Brown SR, Wadhawan H, Nelson RL. Surgery for faecal incontinence in adults. *Cochrane Database Syst Rev.* 2013;7:Cd001757. Doi: 10.1002/14651858.CD001757.pub4.

Chait PG, Shandling B, Richards HM, Connolly BL. Fecal incontinence in children: Treatment with percutaneous cecostomy tube placement — a prospective study. *Radiology.* 1997;203(3):621-624. Doi: 10.1148/radiology.203.3.9169678.

Hoy NY, Metcalfe P, Kiddoo DA. Outcomes following fecal continence procedures in patients with neurogenic bowel dysfunction. *J Urol.* 2013;189(6):2293-2297. Doi: 10.1016/j.juro.2012.12.052.

Itkin M, DeLegge MH, Fang JC, et al. Multidisciplinary practical guidelines for gastrointestinal access for enteral nutrition and decompression from the Society of Interventional Radiology and American Gastroenterological Association (AGA) Institute, with endorsement by Canadian Interventional Radiological Association (CIRA) and Cardiovascular and Interventional Radiological Society of Europe (CIRSE). *Gastroenterol.* 2011;141(2):742-765. Doi: 10.1053/j.gastro.2011.06.001.

Khan WU, Satkunasingham J, Moineddin R, et al. The percutaneous cecostomy tube in the management of fecal incontinence in children. *J Vasc Interv Radiol.* 2015;26(2):189-195. Doi: 10.1016/j.jvir.2014.10.015.

Li C, Shanahan S, Livingston MH, Walton JM. Malone appendicostomy versus cecostomy tube insertion for children with intractable constipation: A systematic review and meta-analysis. *J Pediatr Surg.* 2018;53(5):885-891. Doi: 10.1016/j.jpedsurg.2018.02.010.

Miller ZA, Mohan P, Tartaglione R, Narayanan G. Bowel obstruction: Decompressive gastrostomies and cecostomies. *Semin Intervent Radiol.* 2017;34(4):349-360. Doi: 10.1055/s-0037-1608706.

Mohamed H, Wayne C, Weir A, Partridge EA, Langer JC, Nasr A. Tube cecostomy versus appendicostomy for antegrade enemas in the management of fecal incontinence in children: A systematic review. *J Pediatr Surg*. 2020;55(7):1196-1200. Doi: 10.1016/j.jpedsurg.2020.01.011.

Mounsey A, Raleigh M, Wilson A. Management of constipation in older adults. *Am Fam Physician*. 2015;92(6):500-504. <https://pubmed.ncbi.nlm.nih.gov/26371734/>. National Institute of Diabetes and Digestive and Kidney Diseases. Bowel control problems (fecal incontinence). <https://www.niddk.nih.gov/health-information/digestive-diseases/bowel-control-problems-fecal-incontinence>. Published 2022.

National Institute of Diabetes and Digestive and Kidney Diseases. Bowel Control Problems (Fecal Incontinence). <https://www.niddk.nih.gov/health-information/digestive-diseases/bowel-control-problems-fecal-incontinence>. Published 2022.

Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. *Dis Colon Rectum*. 2015;58(7):623-636. Doi: 10.1097/DCR.0000000000000397.

Siminas S, Losty PD. Current surgical management of pediatric idiopathic constipation: A systematic review of published studies. *Ann Surg*. 2015;262(6):925-933. Doi: 10.1097/SLA.0000000000001191.

U. S. Food and Drug Administration. 510(k) Premarket Notification database — searched using 510(k) number K982500. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K982500>. Updated December 12, 2022.

Policy updates

2/2016: initial review date and clinical policy effective date: 6/2016

1/2018: Policy references updated.

1/2019: Policy references updated. Policy ID changed.

3/2000: Policy references updated.

3/2021: Policy references updated.

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated.