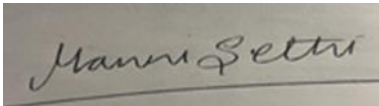


Prior Authorization Review Panel
MCO Policy Submission

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: AmeriHealth Caritas Pennsylvania & Keystone First		Submission Date: 4/1/2025	
Policy Number: ccp.1223		Effective Date: 7/2016 Revision Date: 3/1/2025	
Policy Name: Cecostomy for fecal incontinence			
Type of Submission:		Type of Policy:	
☐ New Policy	☒ Prior Authorization Policy		
☒ Revised Policy*	☐ Base Policy		
☐ Annual Review- no revisions	☐ Experimental/Investigational Policy		
	☐ Statewide PDL		
	☐ Other:		
*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:			
Name of Authorized Individual (Please type or print):		Signature of Authorized Individual:	
Manni Sethi, MD, MBA, CHCQM			

Cecostomy for fecal incontinence

Clinical Policy ID: CCP.1223

Recent review date: 3/2025

Next review date: 7/2026

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 when all of the following criteria are met (Bordeianou, 2023; Itkin, 2011; Jonker, 2025; Li, 2018; Mohamed, 2020):

- Members aged four years or older.
- Members who are 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 are investigational/not clinically proven and, therefore, 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 (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 (Radiologic Society of North America, 2024).

Findings

Guidelines

Current guidelines reflect limited consensus on the benefit of cecostomy for refractory defecatory disorders as an alternative to appendicostomy (Malone procedure). While cecostomy is more widely studied and applied in pediatric populations, formal guidelines are lacking. For adults, cecostomy tubes may have a limited role in select patients with refractory fecal incontinence who wish to avoid permanent fecal diversion, but long-term efficacy is uncertain.

An American Gastroenterological Association and the Society of Interventional Radiology joint guideline suggests several pre-procedural measures for cecostomy, 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 guideline 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).

The American Gastroenterological Association stated antegrade continence enemas were not an effective long term solution for adults with defecatory disorders. In two limited case series with short follow up periods, enemas delivered via appendicostomy or button cecostomy had lower success rates in adults than in children (50% versus 80%). Long-term complications (e.g., stoma stenosis or leakage, or treatment failure occurred in more than 50% at three years), which required revision, reversal, or conversion to a formal stoma (Bharucha, 2017).

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 guidelines for adults with fecal incontinence. The guideline does not mention cecostomy as a surgical intervention (Assmann, 2022).

The American Society of Colon and Rectal Surgeons reviewed 182 sources on fecal incontinence, highlighting cecostomy in two case series with a total of 134 adults. At 22 to 48 months follow-up, 78% to 100% of patients continued using antegrade enemas via cecostomy tubes (Patel, 2015). Additionally, a retrospective study (n = 75) showed a decrease in mean Wexner scores from 14.3 to 3.4 up to 48 months post-treatment (Chéreau, 2011). Despite limited evidence, cecostomy tubes may be considered for highly motivated patients with refractory fecal incontinence, aiming to avoid permanent fecal diversion (Bordeianou, 2023). The Society also reviewed treatments for chronic constipation in adults but did not mention cecostomy as an option (Alavi, 2024).

Evidence review

The best available evidence supporting the safety and efficacy of cecostomy consists largely of single-institution, retrospective case series involving children with refractory defecatory disorders. The supportive evidence in adult populations is far more limited.

There is considerable practice variation regarding the optimal age at time of tube placement, type of tube placement for antegrade continence enemas, and surgeons' preferences, even among specialized pediatric colorectal centers. The most common indication for cecostomy was idiopathic/refractory constipation, whereas anorectal malformation was the most common indication for Malone and Neo-Malone procedures (Kwon, 2024).

From systematic review evidence, cecostomy is a safe and effective alternative to Malone appendicostomy for developing antegrade continence enema access that can be done concurrently with other procedures. While each procedure has advantages and disadvantages with respect to surgical and patient-related outcomes, studies assessing patient and parent satisfaction reported high satisfaction rates with both. Additional research based on diagnosis and age is needed to clarify who would benefit most from these procedures (Jonker, 2025).

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 complications after appendicostomy were stenosis (16.7%) followed by leakage (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%, $P = .01$). 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) (Li, 2018).

In adults with severe constipation, Duchalais (2015) followed a series of 19 patients for one year following successful percutaneous endoscopic cecostomy placement. Complications were minor, including chronic wound pain ($n = 9$), serous leakage ($n = 7$), superficial wound infection ($n = 2$) and accidental catheter removal ($n = 2$). Patients achieved significant functional relief and improvement in quality of life, allowing approximately 75% of patients to suspend laxatives and retrograde enemas. However, five patients required cecostomy removal because of chronic wound pain.

In 2025, we reorganized the findings section and updated the references. No policy changes are warranted.

References

On January 22, 2025, 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.

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Policy updates

2/2016: initial review date and clinical policy effective date: 7/2016

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.

3/2025: Policy references updated.