



**SANDHILLS
CENTER**



Cecostomy for fecal incontinence

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Next review date: 7/2023

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

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center'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 Sandhills Center 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. Sandhills Center 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. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

Cecostomy is clinically proven and, therefore, medically necessary for fecal incontinence when all of the following criteria are met (Itkin, 2011; 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 clinical indications 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

- Lifestyle and dietary modifications.
- 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, 2021). 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 four systematic reviews or evidence reports, three 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. One retrospective cohort study compared the Malone antegrade continence enema procedure to a cecostomy button in adults and children with neurogenic bowel dysfunction (Hoy, 2013). Both surgical and percutaneous cecostomy procedures have been reported in the literature, but a number of studies favors percutaneous placement. For antegrade continence enema delivery, the Chait Trapdoor catheter was used in the majority of patients.

The overall quality of the evidence is low, and the evidence lacks prospective comparison to other surgical alternatives and clearly defined, consistent inclusion criteria and outcome measures. The evidence suggests that cecostomy may improve some symptoms of chronic refractory constipation with fecal incontinence and pseudo-obstruction. The effect on quality of life was inconsistent. Minor complications associated with the procedure were common and similar to those seen with percutaneous gastrostomy and percutaneous feeding tubes, including local infection at the wound or antegrade continence enema site, catheter-related complications, and the development of granulation tissue. These complications were usually mild and easily treatable, and no major complications associated with the procedure were reported. Limited evidence suggests no difference in complication rates between endoscopic and radiologic placement (Itkin, 2011).

However, prospective comparative studies are needed to determine how cecostomy compares with other surgical or minimally invasive procedures (e.g., colostomy, artificial bowel sphincter or dynamic graciloplasty) in functional outcomes, post-procedural complications and quality of life. 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.

Improved patient selection criteria are needed to select the appropriate patients with chronic refractory fecal incontinence for the respective open and minimally invasive procedures. Clinical indications for adults included chronic colonic pseudo-obstruction, colonic obstruction, chronic refractory constipation with fecal incontinence, acute traumatic anal sphincter rupture, major defect in the external anal sphincter in the presence of gross fecal incontinence and rectal prolapse. Cecostomy was used in children mainly with neurologic disease (e.g., spina bifida, spinal cord injury, cerebral palsy) that results in severe refractory fecal incontinence.

Absolute contraindications to C-tube placement include previous abdominal surgical procedures; active peritonitis, colitis, and 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 (Itkin, 2011).

According to one multidisciplinary guideline, percutaneous cecostomy is indicated for patients with neurologic disease that results in fecal incontinence to facilitate cleansing enemas and for treatment of chronic refractory constipation, chronic colonic pseudo-obstruction and colonic obstruction (Itkin, 2011). The American Society of Colon and Rectal Surgeons' guideline mentions cecostomy, noting the limited evidence supporting the procedure, but recommends neither for nor against its use (Paquette, 2015).

The demand for percutaneous cecostomy for fecal incontinence may increase, despite a lack of high-quality evidence. Both surgeons and patients may demand it, since the procedure may delay the need for more invasive surgical treatments. The Society of Interventional Radiology and American Gastroenterological Association Institute issued recommendations for pre-procedural risk assessment to identify candidates for cecostomy (Itkin, 2011). Pre-procedure assessment involves evaluation of procedural risk from bleeding and patient's probability of a thromboembolic complication occurring should anticoagulation or antiplatelet therapy be stopped before the procedure.

Cecostomy is considered a high-risk procedure. Among patients receiving anticoagulant therapy, those with a mitral metal valve, atrial fibrillation with prosthetic valve, atrial fibrillation with mitral valve stenosis, deep venous thrombosis less than three months after the event, and thrombophilia syndromes are considered high risk (Itkin, 2011). Among patients receiving antiplatelet therapy, those with coronary artery disease with drug-eluting stents less than 12 months out, or with coronary artery disease with bare stents less than one month out, are considered high risk.

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).

The American Gastroenterological Association's recommendations that apply to cecostomy for a patient with a low-risk condition are (Itkin, 2011):

- If on warfarin, warfarin should be stopped five days before the procedure.
- The International Normalized Ratio should be checked on the day of the procedure and should be confirmed to be lower than 1.5.
- Warfarin may be started later on the night of the procedure, with International Normalized Ratio checked one week later.
- Clopidogrel therapy should be discontinued seven days before the procedure, with aspirin therapy continued.
- If the patient is not receiving aspirin, aspirin therapy should be started as the patient discontinues receiving clopidogrel.

The American Gastroenterological Association's recommendations that apply to cecostomy for a patient with a high-risk condition are (Itkin, 2011):

- Warfarin should be stopped five days before the procedure.
- A therapeutic dose of low molecular weight heparin should be substituted, with the dose withheld on the morning of the procedure.
- On the night of the procedure, warfarin should be restarted at the full therapeutic dose.

- For clopidogrel therapy, the clinician should discuss the necessity of the procedure first with the primary care physician, as risk is significant. If the procedure is deemed to be essential, clopidogrel should be stopped seven days before surgery and the patient given aspirin therapy in the interim.
- Clopidogrel therapy may be restarted on the morning after the procedure.

The Society of Interventional Radiology's recommendations for cecostomy include (Itkin, 2011):

- International Normalized Ratio: If greater than 1.5, correct until it is less than 1.5.
- Platelets: If platelet count is lower than 50,000/ μ L, administer transfusion until the count is greater than 50,000/ μ L.
- Clopidogrel: Withhold for five days before the procedure.
- Aspirin: Do not withhold.
- Low molecular weight heparin (therapeutic dose): Withhold one dose before the procedure.

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

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%). 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).

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 (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, 2014).

References

On December 23, 2021, 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.

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