Clinical Policy Title: Cecostomy for fecal incontinence

Clinical Policy Number: 08.01.06

Effective Date: July 1, 2016
Initial Review Date: February 17, 2016
Most Recent Review Date: March 6, 2018
Next Review Date: March 2019

Related policies:

CP# 08.02.04 Injectable bulking agents for fecal incontinence

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’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 Select Health of South Carolina 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. Select Health of South Carolina’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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of cecostomy to be clinically proven and, therefore, medically necessary for treatment of fecal incontinence when all of the following criteria are met (DeFreest, 2014; Hayes, 2015; Khan, 2015):

- Persons ages 4 years or older.
- 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:

Policy contains:
- Chronic constipation.
- Fecal incontinence (FI).
- Open and percutaneous cecostomy.
– Facilitating an antegrade continence enema in persons with fecal incontinence secondary to neurologic disease.
– Providing cecal decompression for patients with chronic refractory constipation, chronic colonic pseudo-obstruction, or colonic obstruction.

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 patients receiving anticoagulant or antiplatelet therapy:
  - International Normalized Ratio (INR) less than 1.5.
  - Platelet count greater than 50,000/µL.

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; Dobson, 2009; Paquette, 2015). A working definition from the American Society of Colon and Rectal Surgeons (ASCRS) encompasses several
factors: “The uncontrolled passage of feces or gas over at least one month’s duration, in an individual of at least 4 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 [NIDDK], 2016). 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 (NIDDK, 2016). Surgery may be indicated for fecal incontinence refractory to conservative treatment or for colonic pseudo-obstruction.

Cecostomy:

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., in treating fecal incontinence in children (Chait, 1997; 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, 2016).

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 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.

Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 16, 2018. Search terms were: “cecostomy” [MeSH] and free text terms “cecostomy” and “caecostomy.”
We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews**.

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

We identified three 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 (QOL) 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 (Hayes, 2011a; Hayes, 2011b; 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 ASCRS 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 (SIR) and American Gastroenterological Association (AGA) 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. Table 1 presents risk determination based on patient condition (Itkin, 2011).

Table 1. SIR and AGA determination of risk for patients receiving anticoagulant or antiplatelet therapy based on clinical condition.

<table>
<thead>
<tr>
<th>Level of risk</th>
<th>Patients receiving anticoagulant therapy</th>
<th>Patients receiving antiplatelet therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk</td>
<td>• Aortic metal valve.</td>
<td>• Coronary artery disease (CAD) without stents.</td>
</tr>
<tr>
<td></td>
<td>• Atrial fibrillation without valvular disease.</td>
<td>• CAD with drug-eluting stents &gt; 12 months out.</td>
</tr>
<tr>
<td></td>
<td>• Xenograft valve.</td>
<td>• CAD with bare stents &gt; one month out.</td>
</tr>
<tr>
<td></td>
<td>• Deep vein thrombosis &gt; three months after event.</td>
<td>• Cerebrovascular accident.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Arteriosclerotic peripheral vascular disease.</td>
</tr>
<tr>
<td>High risk</td>
<td>• Mitral metal valve.</td>
<td>• CAD with drug-eluting stents &lt; 12 months out.</td>
</tr>
<tr>
<td>Level of risk</td>
<td>Patients receiving anticoagulant therapy</td>
<td>Patients receiving antiplatelet therapy</td>
</tr>
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|               | • Atrial fibrillation with prosthetic valve.  
|               | • Atrial fibrillation with mitral valve stenosis.  
|               | • Deep venous thrombosis < three months after event.  
|               | • Thrombophilia syndromes.                | • CAD with bare stents < one month out. |

AGA 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 INR 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 INR 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.

AGA 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.

SIR recommendations for cecostomy include (Itkin, 2011):

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

**Policy updates:**

In 2018, five publications were added to the reference list, including two studies of patient and family decisional regret or satisfaction. Both of the latter were added to the summary of clinical evidence.
Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
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</table>
| Meenakshi-Sundaram (2018)        | **Key points:**  
  - This retrospective single site study examined a sample of 81: 32 patients who received Malone antegrade continence enema as children during 2006-2016, and 49 caregivers, using the Decisional Regret Scale, and correlated the results with demographics, surgical outcomes, and complications. Mean follow-up was 49 months.  
  - Of 81 total responses, over half (53%) demonstrated decisional regret. Nearly half (47%) demonstrated mild regret and 6% displayed moderate to severe regret. In univariate analysis, there was no statistical association with gender, complications or performance of concomitant procedures. Regression analysis showed that incontinence was strongly associated with decisional regret (Odds Ratio (OR) 4.4, 95% CI 1.1-18.1, \( p < 0.001 \)). Regret increased with age at surgery, especially among patients operated on at 13 to 15 years of age (OR 2.6, 95% CI 1.0-6.4 for age 13 years; OR 2.9, 95% CI 1.1-7.8 for age 14 years; OR 3.1, 95% CI 1.1-8.8 for age 15 years).  
  - The authors conclude that surgical techniques to achieve continence may reduce decisional regret, and that age-related findings should be discussed with families as the age at which surgery takes place may be affected.                                                                                                                                 |
| Bevill (2017)                    | **Key points:**  
  - This retrospective study evaluated use of the Chait cecostomy tube in children with spinal dysraphisms and constipation, through a questionnaire completed by patients and/or their families at a single site. A total of 86 persons participated: 53 with a cecostomy tube and 33 with no tube.  
  - Management of constipation was rated higher among those with a cecostomy tube (\( p < 0.001 \)). Among those with a tube, nearly half (48%) had complete or near complete continence, 40% had partial fecal incontinence, and 12% remained incontinent. The vast majority (88%) were satisfied with the tube, and 92% would have it placed again. Additionally, hygiene, independence, and social confidence increased over baseline significantly.  
  - Complications among those who underwent cecostomy included granulation tissue that needed treatment (60%) and irrigation-associated pain (24%).                                                                                                                                                                                                 |
| Hayes (2015)                     | **Key points:**  
  - Search and summary report without analysis of one case series (21 patients), one retrospective single-center study (eight patients), one retrospective case series (54 patients) and one retrospective standardized questionnaire (23 patients).  
  - Overall quality: low. Retrospective, single-arm studies, lacking clear descriptions of patient populations and outcomes.  
  - Percutaneous endoscopic cecostomy placement is safe and achieved satisfying functional and quality of life results in 75% of patients. The cecostomy was removed in 25% of patients because of chronic wound pain. Outcomes were comparable with percutaneous endoscopic cecostomy or surgically or fluoroscopically placed cecostomy in some patients with recurrent colonic pseudo-obstruction or chronic intractable constipation.  
  - There was insufficient published evidence to assess the safety and/or impact on health.                                                                                                                                                                                                                                           |
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| Khan (2015) | **Key points:**  
- This paper describes a retrospective case series of 290 children (mean age 10.1 years) with fecal incontinence who underwent percutaneous C-tube placement and subsequent tube management between June 1994 and March 2009 and followed until March 2012.  
- The procedure achieved technical success: tube placement (98%), exchange to a low-profile tube (92%). After routine exchanges to low-profile tubes, a minority of patients experienced problems and most problems were minor.  
- Authors’ conclusions: The percutaneous cecostomy procedure is feasible and safe for fecal incontinence in the pediatric population. |
| DeFreest (2014) | **Key points:**  
- This is a report of a single center retrospective series of 16 children (eight boys). Mean age at procedure was 11 years (range 6 – 16 years). Diagnoses were functional constipation with soiling (14 patients), incontinence after surgery for Hirschsprung’s disease (one patient), and constipation secondary to mitochondrial disease (one patient). Seven had significant developmental or psychiatric problems. Mean follow-up after initial cecostomy = 22 months (range, 6 – 51 months).  
- Authors’ conclusions: Laparoscopic-assisted percutaneous cecostomy has an excellent safety profile and patient comfort. The procedure is simple, secure, and reversible. Cessation of fecal soiling with no need for diapers achieved in half of the patients. Associated psychiatric or behavioral problems may predict poor response to antegrade continence enema. |
| Hoy (2013) | **Key points:**  
- This retrospective chart review examines data on patients who underwent Malone antegrade continence enema (26 patients) or cecostomy (23 patients) at the University of Alberta between January 2006 and January 2011.  
- No significant differences were found between Malone antegrade continence enema and cecostomy button with respect to fecal incontinence or complication rates at one year follow-up. Each approach poses unique challenges. |
| Hayes (2011b, updated 2012, archived 2014) | **Key points:**  
- This systematic review examined three small retrospective case series (48 total patients). Cecostomy was performed in two studies, open surgery in one study for colonic decompression or delivery of antegrade continence enema (using Chait device or gastrostomy button).  
- The overall quality was very low. The studies were retrospective and uncontrolled and had serious methodological flaws. They relied on subjective study outcomes and had incomplete analysis of data.  
- Cecostomy is feasible in adults with fecal incontinence. Cecostomy may improve some symptoms of chronic refractory constipation with fecal incontinence and pseudo-obstruction. The effect on quality of life was inconsistent. Complications with either procedure were mild with no need for surgery. |
Citation | Content, Methods, Recommendations
---|---
Hayes (2011a, updated 2012, archived 2014) | **Key points:**
- This systematic review examined one prospective case series and five retrospective case series (378 total children) with chronic refractory constipation or chronic fecal incontinence was secondary to a variety of diagnoses. Either percutaneous endoscopic cecostomy or an open surgical technique used. Chait trapdoor catheter was used for antegrade continence enema delivery in the majority of patients. Follow-up took place between one month and seven years.
- The overall quality of the data was low due to primarily retrospective design, lack of control groups, and use of subjective outcome measures. There were no well-designed prospective trials.
- Procedural complications were relatively minor and treatable. They were related to tube placement, integrity or infection. Most frequently reported: granulation tissue (range 4% to 68%) and leakage along the button (range 42% to 48%).
- The review concluded that there was limited evidence that percutaneous endoscopic cecostomy may improve symptoms of chronic fecal incontinence in children by reducing the number of fecal incontinence episodes per week and improving some measures of quality of life.
- There is a need for more data on the relative efficacy and safety of percutaneous endoscopic cecostomy and surgical cecostomy. Additionally, more definitive patient selection criteria are needed.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>44188</td>
<td>Laparoscopy, surgical, colostomy or skin level cecostomy</td>
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<td>44300</td>
<td>Placement of enterostomy or cecostomy for decompression</td>
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<td>49442</td>
<td>Insertion of cecostomy or other colonic tube, percutaneous</td>
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<thead>
<tr>
<th>ICD-10 CM Code</th>
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<td>ICD-10 CM Code</td>
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<td>K59.01</td>
<td>Slow transit constipation</td>
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<td>K59.02</td>
<td>Outlet dysfunction constipation</td>
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<td>K59.04</td>
<td>Chronic idiopathic constipation</td>
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<td>K59.09</td>
<td>Chronic constipation</td>
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<tr>
<td>R15.9</td>
<td>Fecal incontinence NOS</td>
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