Clinical Policy Title: Cecostomy for fecal incontinence

Keystone VIP Choice has developed clinical policies to assist with making coverage determinations. Keystone VIP Choice’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 VIP Choice 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 VIP Choice’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 VIP Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone VIP Choice will update its clinical policies as necessary. Keystone VIP Choice’s clinical policies are not guarantees of payment.

Coverage policy

Keystone VIP Choice considers the use of cecostomy to be clinically proven and, therefore, medically necessary for treatment of fecal incontinence (FI) when all of the following criteria are met:

- Persons age 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:
  - Facilitating an antegrade continence enema (ACE) in persons with FI 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

FI is a debilitating symptom resulting from many causes. There are multiple definitions of FI that vary according to target population (adults versus children), symptoms, symptom duration and method used (Paquette, 2015; Dobson, 2009). 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 4 years of age, who had previously achieved control” (Paquette, 2015).

Variation in definition and under-communicating the symptom to providers make precise estimates of FI difficult to obtain. Nonetheless, FI is a common symptom with a prevalence that ranges from at least 7 percent to 15 percent in community-dwelling adults (Bharucha, 2015). The estimated prevalence of FI in children ages 5 years to 6 years, 4 years to 7 years and 11 years to 12 years is 4 percent, 4.4 percent and 1.6 percent, respectively (Dobson, 2009).

Community-based studies suggest the strongest independent risk factors for FI are bowel disturbances (particularly diarrhea), the symptom of rectal urgency and burden of chronic illness (Bharucha, 2015). Advanced age, female gender, disease burden (comorbidity count, diabetes), anal sphincter trauma
(obstetrical injury, prior surgery) and decreased physical activity increase the risk of FI. Potentially modifiable risk factors include smoking, obesity and inappropriate cholecystectomy.

Multiple factors control bowel function. These include anal sphincter pressure, anorectal sensation, rectal compliance, colonic transit time, and stool volume and consistency. Deficits in any of these factors can cause FI. The type (urge, passive or combined), cause and symptom severity provide the basis for classifying FI (Bharucha 2015). The causes are broadly classified as organic or functional. Organic causes include neurogenic disorders, inflammatory disorders, obstetric trauma and anorectal anomalies. Functional FI encompasses bowel disturbances, most commonly constipation with or without fecal impaction or overflow diarrhea, without evidence of a structural or biochemical explanation.

FI is a clinical diagnosis primarily based on history and examination. In situations where the clinical cause is not apparent, the differential diagnosis may include anal manometry, anal ultrasound, colonic transit study, magnetic resonance imaging (MRI), defecography, flexible sigmoidoscopy or colonoscopy, and anal electromyography (EMG) (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016).

Initial treatment for FI 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 FI refractory to conservative treatment or for colonic pseudo-obstruction.

**Cecostomy:**

Cecostomy is the creation of an opening in the cecum to facilitate an ACE or to provide cecal decompression (Itkin, 2011). The procedure involves 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 FI in children (Chait, 1997; Itkin, 2011).

Standard colonoscopy preparation with a polyethylene glycol solution is administered prior to the procedure. For open cecostomy, the hospital length of stay ranges from five days to 10 days. Patients undergoing percutaneous cecostomy typically have a shorter hospital stay. Approximately one week after the procedure, the patient begins self-administering ACEs through the C-tube, and an individualized irrigation routine is established. After six weeks, the temporary catheter is exchanged for a semi-permanent, 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 semi-permanent catheters is performed annually.

**Regulation:**

Cecostomy is a procedure and, therefore, is not subject to United States Food and Drug Administration (FDA) approval or clearance. However, the cecostomy tube/catheter used in this procedure is subject to FDA approval or clearance. One commonly used device is the Chait Cecostomy Catheter (Cook Inc., Bloomington, Indiana), which received FDA clearance on January 27, 1999, as a Class II device, after a determination of substantial equivalence to predicate devices (FDA, 2016).
**Searches**

Keystone VIP Choice 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 13, 2016. 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 ACE (MACE) 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 the number of studies favors percutaneous placement. For ACE 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 FI 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 ACE 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, postprocedural complications and QOL. One Cochrane review found a striking lack of high-quality randomized controlled trials (RCTs) on FI surgery, with existing RCTs
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 FI for the respective open and minimally invasive procedures. Clinical indications for adults included chronic colonic pseudo-obstruction, colonic obstruction, chronic refractory constipation with FI, acute traumatic anal sphincter rupture, major defect in the external anal sphincter in the presence of gross FI 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 FI. 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 FI 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 FI 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>
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<tbody>
<tr>
<td>Low risk</td>
<td>• Aortic metal valve.</td>
<td>• Coronary artery disease (CAD) without stents.</td>
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<tr>
<td></td>
<td>• Atrial fibrillation without valvular disease.</td>
<td>• CAD with drug-eluting stents &gt; 12 months out.</td>
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<tr>
<td></td>
<td>• Xenograft valve.</td>
<td>• CAD with bare stents &gt; one month out.</td>
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<tr>
<td></td>
<td>• Deep vein thrombosis &gt; three months after event.</td>
<td>• Cerebrovascular accident.</td>
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<tr>
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<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></td>
<td>• Atrial fibrillation with prosthetic valve.</td>
<td>• CAD with bare stents &lt; one month out.</td>
</tr>
<tr>
<td></td>
<td>• Atrial fibrillation with mitral valve stenosis.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Deep venous thrombosis &lt; three months after event.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thrombophilia syndromes.</td>
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</tbody>
</table>
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.
- One 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.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td></td>
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<tr>
<td>Hayes (2015)</td>
<td></td>
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<tr>
<td>Cecostomy for slow transit constipation in adults</td>
<td>Key points:</td>
</tr>
<tr>
<td></td>
<td>- Search and summary report without analysis of one case series (n = 21), one retrospective single-center study (n = 8), one retrospective case series (n = 54) and one retrospective standardized questionnaire (n = 23).</td>
</tr>
<tr>
<td></td>
<td>- Overall quality: low. Retrospective, single-arm studies, lacking clear descriptions of patient populations and outcomes.</td>
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<td></td>
<td>- Percutaneous endoscopic cecostomy (PEC) placement is safe and achieved satisfying functional and quality of life results in 75% of patients. PEC removed in 25% of patients because of chronic wound pain. Comparable outcomes with PEC or surgically or fluoroscopically-placed cecostomy in some patients with recurrent colonic pseudo-obstruction or chronic intractable constipation.</td>
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<tr>
<td></td>
<td>- Insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of cecostomy for treatment of slow transit constipation.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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<tr>
<td>----------------------------------------------</td>
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<tr>
<td>Khan (2015)</td>
<td><strong>Key points:</strong></td>
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| Percutaneous C-tube in the management of FI in children | • Retrospective case series of 290 children (mean age 10.1 years) with FI who underwent percutaneous C-tube placement and subsequent tube management between June 1994 and March 2009 and followed until March 2012.  
  • 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 FI in the pediatric population. |
| DeFreest (2014)                               | **Key points:**                                                                                    |
| Laparoscopic-assisted percutaneous cecostomy for ACE | • 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 (n = 14), incontinence after surgery for Hirschsprung's disease (n = 1) and constipation secondary to mitochondrial disease (n=1). 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 ACE. |
| Hoy (2013)                                    | **Key points:**                                                                                    |
| Malone ACE (MACE) versus cecostomy button in patients with neurogenic bowel dysfunction | • Retrospective chart review of patients who underwent MACE (26 patients) or cecostomy (23 patients) at the University of Alberta between January 2006 and January 2011.  
  • No significant differences between MACE and cecostomy button with respect to FI or complication rates at one year follow up. Each approach poses unique challenges. |
| Hayes (2011a, updated 2012, archived 2014)     | **Key points:**                                                                                    |
| Cecostomy for treatment of FI in adults       | • Systematic review of three small retrospective case series (48 total patients). PEC performed in two studies, open surgery in one study for colonic decompression or delivery of ACE (using Chait device or gastrostomy button).  
  • Overall quality: very low. Retrospective and uncontrolled with serious methodological flaws, used subjective study outcomes, and had incomplete analysis of data.  
  • Cecostomy is feasible in adults with FI. Cecostomy may improve some symptoms of chronic refractory constipation with FI and pseudo-obstruction. The effect on QOL was inconsistent. Complications with either procedure were mild with no need for surgery. |
| Hayes (2011b, updated 2012, archived 2014)     | **Key points:**                                                                                    |
| Cecostomy for treatment of FI in children     | • Systematic review of one prospective case series and five retrospective case series (378 total children) with chronic refractory constipation or chronic FI secondary to a variety of diagnoses. PEC or open surgical technique used. Chait trapdoor catheter was used for ACE delivery in the majority of patients. Follow-up one month to seven years.  
  • Overall quality: low. Retrospective design, no control groups and use of subjective outcome measures; no well-designed prospective trials.  
  • Procedural complications were relatively minor and treatable 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%).  
  • Limited evidence that PEC may improve symptoms of chronic FI in children by reducing the number of FI episodes per week and improving some measures of QOL.  
  • Relative efficacy and safety of PEC or surgical cecostomy and more definitive patient selection criteria are needed. |
**Glossary**

**Cecostomy** — Surgical creation of an artificial opening or fistula into the cecum.

**Cecum** — The first portion of the large bowel, which is situated in the lower-right quadrant of the abdomen. Receives fecal material from the small bowel (ileum).

**Clopidogrel (bisulfate)** — An antiplatelet medicine used to reduce the risk of heart attacks, strokes and other clot-related conditions in patients who have had a previous heart attack, stroke or problems with the circulation in the arms and legs.

**Colonic (intestinal) pseudo-obstruction** — A rare disorder of gastrointestinal motility with symptoms that resemble a blockage or obstruction of the bowel but are due to altered and inefficient peristalsis.

**Constipation** — A condition of fewer than three bowel movements a week or hard, dry and small bowel movements that are painful or difficult to pass (NIDDK, 2016). Chronic constipation is constipation that persists over several weeks.

**Fecal incontinence** — Lack of bowel control, leading to involuntary loss of bowel contents including gas, liquid stool elements and mucus, and solid feces.

**Percutaneous** — Through the skin, referring to surgery with access to underlying structures through a skin incision.

**Rectal (fecal or bowel) urgency** — A sudden, irresistible need to have a bowel movement.

**Slow transit constipation** — An incurable disorder characterized by the reduced motility (spontaneous movement) within the large intestine, caused by abnormalities of the enteric nerves. Leads to chronic problems, such as constipation and uncontrollable soiling. Formerly known as neuronal intestinal dysplasia.

**References**

Professional society guidelines/other:


**Peer-reviewed references:**


Clinical trials:

Searched clinicaltrials.gov on January 27, 2016, using terms faecal incontinence OR fecal incontinence OR constipation | Open Studies | cecostomy OR caecostomy OR caecostomie. Two studies found, two relevant.


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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<tr>
<td>44300</td>
<td>Placement of enterostomy or cecostomy for decompression</td>
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<tr>
<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>
<th>Description</th>
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<tbody>
<tr>
<td>K59.00</td>
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<td>K59.01</td>
<td>Slow transit constipation</td>
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<tr>
<td>K59.02</td>
<td>Outlet dysfunction constipation</td>
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<tr>
<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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