Fecal Incontinence Evaluation and Treatments

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies
None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

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Fecal incontinence (FI), also known as bowel incontinence, is the loss of bowel control, which causes stool to leak involuntarily from the rectum. FI can range from the occasional leakage of stool to complete loss of bowel control. FI may also occur only occasionally (eg, with bouts of diarrhea) or it may be chronic or recurring.

Causes include, but may not be limited to:

- Damage to the anal sphincter (eg, childbirth, surgery)
- Damage to the pelvic diaphragm
- Diarrhea
- Fecal impaction
- Illnesses that cause the inability to expand and store fecal matter (eg, inflammatory bowel disease [IBD])
- Injury

**Evaluation**

Treatment for FI depends on the type of incontinence and the underlying cause; therefore, prior to treatment for FI, an evaluation must be performed. The initial assessment includes obtaining a history and physical, which may consist of an inspection of the perianal area and a digital rectal exam. Other tests include, but may not be limited to, anorectal manometry, endoscopy, endorectal ultrasound or rectal sensory testing.

**Treatment**

Examples of FI treatments include, but may not be limited to:

**Artificial anal sphincter** (eg, Acticon Neosphincter) is an implantable, fluid filled device that consists of an inflatable silicon cuff, a pressure-regulating balloon and a control pump, which reportedly maintains continence by using the pressure of the fluid filled cuff to occlude the anal canal. When there is a need to defecate (bowel movement), the individual squeezes and releases the pump mechanism, which releases the compressive force around the anal canal.

**Biofeedback** is therapy that utilizes sensors to help the individual identify and contract the anal sphincter muscles, which help maintain continence.
Defecation programs (bowel training) are designed to help the individual who has difficulties setting a schedule for sitting on the toilet at a regular time every day after a meal. This training is designed to help incontinence by regularly emptying the bowels.

Injectable bulking agents (eg, Solesta) involves the injection of collagen, autologous fat or other materials into the anal sphincter area to increase the surface area, which purportedly provides a better seal for the anal canal.

Nonimplantable muscle stimulators (eg, leva Digital Therapeutic System) are devices that reportedly provide pelvic muscle stimulation and biofeedback without implantation of electrodes to aid in the treatment of fecal incontinence. These devices may be combined with a smartphone app that reportedly transmits real-time data of pelvic floor muscle training.

Percutaneous tibial nerve stimulation (PTNS) (eg, Urgent PC, Nuro Percutaneous Neuromodulation System [PTNM]), also known as posterior tibial nerve stimulation, involves the use of nonimplanted electrodes which produce stimulation to the tibial nerve that purportedly travels to the sacral nerve plexus to control FI.

Radiofrequency ablation (eg, Secca System) is a minimally invasive procedure that uses alternating electrical current to cause controlled heating of the tissue in the anal sphincter, which reportedly remodels the treated tissue by stimulating the formation of connective tissue.

Rectal catheters and rectal inserts are being investigated for use in a bedridden, immobilized or incontinent individual. Examples of the systems includes, but may not be limited to, include the Qora Stool Management System, which is comprised of a self-expanding indwelling diverter that anchors in the anorectal junction (without a balloon). It is designed to collapse and expand during peristaltic rectal contractions.46 The Renew Anal Insert is a self-inserted silicone insert that purportedly prevents bowel leakage by resting against the rectum. Another system under study (eg, Contix Fecal Incontinence Management System) is a disposable catheter device that utilizes a balloon that is placed via an injector into the anorectal junction and filled with air. The air is deflated for removal. This device is not currently approved by the US Food & Drug Administration (FDA).

Rectal control system for vaginal insertion (eg, Eclipse system) is a device that includes an inflatable balloon that is placed in the vagina, which upon inflation exerts pressure on the vaginal wall supposedly closing off the rectum. Reportedly, bowel evacuation is completed by deflating the device and re-inflating using an external pump.

Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro, InterStimX) involves the implantation of electrodes at the sacral nerve to improve rectal sensation and anal sphincter muscle control.

Stem cells, specifically adipose tissue-derived stem cells, autologous myoblasts, mesenchymal stem cells are being investigated for the treatment of FI. Purportedly, the injection of stem cells during surgical repair of FI stimulates the formation of granulation tissue, leading to regeneration of the anal sphincter muscles.
Surgical treatment may be performed if there is pelvic floor or anal sphincter muscle injuries. Procedures include, but may not be limited to:

- **Colostomy** is the construction of an artificial opening from the colon through the abdominal wall, which bypasses a diseased portion of the lower intestine and permits the passage of stool to a bag outside of the body; typically used as the last attempt to correct FI.

- **Muscle transposition** is a surgical procedure that uses muscles from another area of the body to encircle and strengthen the anal canal (eg, gluteal or gracilis muscles [dynamic graciloplasty]).

- **Sphincteroplasty** is utilized to repair a defect in the sphincter muscle in which the two ends of the muscle are cut and overlapped onto one another and then sutured into place to restore the complete circle of muscle.

Transanal electrical stimulation utilizes electrical stimulation that is applied to the anal canal to supposedly stimulate muscle contraction.

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**Coverage Determination**

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

_In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:_

**Diagnostic testing for fecal incontinence** will be considered medically reasonable and necessary for the following:

- Anorectal manometry; OR
- Anorectal ultrasonography; OR
- Rectal sensory testing

**Conservative management** will be considered medically reasonable and necessary, which includes, but may not be limited to:

- Biofeedback; OR
- Defecation programs/bowel training; OR
- Diet modification; OR
- Pelvic floor physical therapy; OR
- Pharmacotherapy

**Sacral nerve stimulation** (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro and InterStimX) will be considered medically reasonable and necessary when the following requirements are met:

- Absence of contraindications; AND
- Testing confirms a diagnosis of FI; AND
- Failure of, contraindication to or intolerance of conservative management; AND
- Trial test stimulation that demonstrates 50% or greater improvement in incontinence symptoms during a 14-day trial period.\(^1,4\)

**Removal of a SNS device** will be considered medically reasonable and necessary when the following requirements are met:

- A previously implanted device and/or its associated components cause complications or unintended negative outcomes (eg, adverse change in bowel function, infection, new pain, undesirable stimulation) for the individual

**SNS replacement** will be considered medically reasonable and necessary when the following requirements are met:

- Previously implanted device and/or its associated components are no longer functioning appropriately (eg, defective pulse generator, lead migration) and are no longer under warranty; AND
- Absence of contraindications; AND
- FDA-approved device is being utilized as the replacement

**Surgical treatments for FI** will be considered medically reasonable and necessary when the following requirements are met:

- Anal sphincter repair (eg, sphincteroplasty) for the following indications:
  - Anal sphincter injury; AND
Failure of, contraindication to or intolerance of conservative management; OR

Colostomy for the following indications:

- Failure of, contraindication to or intolerance of conservative management of a minimum of 2 therapies; AND
- Failure of or not a candidate for minimally invasive surgical interventions (e.g., sacral nerve stimulation) or sphincteroplasty

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following incontinence items will not be considered a benefit (statutory exclusion):

- Incontinence collection systems (e.g., perianal fecal collection pouches);
- Incontinence undergarments (e.g., briefs, diapers);
- Rectal catheters (e.g., Contix Fecal Incontinence Management System, Qora Stool Management Kit);
- Rectal inserts (e.g., Renew Insert)

These treatments and services fall within the Medicare program’s statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act).

The following fecal incontinence treatments will not be considered medically reasonable and necessary:

- Adipose tissue-derived stem cells
- Autologous myoblasts or mesenchymal stem cell injections
- Nonimplantable muscle stimulators
- Transanal electrical stimulation

A review of the current medical literature shows that there is no evidence to determine that these services are standard medical treatments. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following fecal incontinence treatments will not be considered medically reasonable and necessary:
Fecal Incontinence Evaluation and Treatments

- Artificial anal sphincter (eg, Acticon Neosphincter); OR
- Injectable bulking agents (eg, Solesta); OR
- Percutaneous tibial nerve stimulation (eg, Urgent PC); OR
- Rectal control system for vaginal insertion (eg, Eclipse system); OR
- Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro and InterStimX) if the following contraindications are present:
  - 17 years of age or younger; OR
  - Presence of anorectal malformation (eg, congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae and/or chronic inflammatory bowel disease); OR
  - Bilateral stimulation; OR
  - Individual not capable of operating the device: OR
  - Pregnancy; OR
    - Presence of progressive, systemic neurologic diseases (eg, multiple sclerosis, Parkinson’s disease)\textsuperscript{51,52}; OR
- Transanal radiofrequency therapy (eg, Secca System)

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

**Summary of Evidence**

**Artificial Anal Sphincter**
Even though the use of an artificial sphincter device has been correlated with clinical improvements for the treatment of FI, its use is limited by complications, which include explantation in up to one-third of individuals.\textsuperscript{37} Many of these devices have shown unacceptable complication or explantation rates and have only been evaluated in small numbers of individuals.\textsuperscript{1}

**Injectable Bulking Agents**
Data regarding the long-term effects of sphincter bulking injections are lacking.\(^2\) A total of 24 studies have been published that describe a variation of injection sites, the implanted materials and techniques. However, the results have been inconsistent, and interpretation was challenging due to the multiple compounds and injection techniques that were utilized.\(^6\)

**Percutaneous Tibial Nerve Stimulation (PTNS)**
Evidence is insufficient, conflicting or poor and there is insufficient evidence to determine net benefit versus harms; additional research is recommended.\(^{29}\) Until further evidence is available, PTNS should not be used for the treatment of fecal incontinence in clinical practice.\(^4\) PTNS is not approved for the treatment of fecal incontinence.\(^2\)

**Rectal Control System for Vaginal Insertion**
In a study of 61 women who were fitted with the Eclipse device, an 85% success rate was reported at a three-month follow-up. However, limited studies prevent determination of efficacy in the long-term.\(^{37}\)

**Sacral Nerve Stimulation**
According to the manufacturer of the device listed above, the indications are considered either contraindications or warnings.\(^{30}\)

**Transanal Radiofrequency Therapy**
Due to the limited available data, alternative methods should be pursued before considering radiofrequency delivery.\(^6\) Radiofrequency should not be offered routinely as there is a lack of high-quality studies to support its use.\(^2\)

### Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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<td>38240</td>
<td>Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor</td>
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<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
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<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
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<td>Revision or removal of peripheral neurostimulator electrode array</td>
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### Fecal Incontinence Evaluation and Treatments

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<td>64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
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<td>90913 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)</td>
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### CPT® Category III Code(s)

#### Description

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<td>A4330 Perianal fecal collection pouch with adhesive, each</td>
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<td>A4335 Incontinence supply; miscellaneous</td>
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<td>A4553 Nondisposable underpads, all sizes</td>
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**References**


### Change Summary

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