Medical Guideline Disclaimer

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Definitions

EmblemHealth utilizes the definitions in the table below for this guideline.

<table>
<thead>
<tr>
<th>Severe fecal incontinence</th>
<th>Involuntary loss of solid/liquid stool on a weekly, or more, frequent basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conservative medical interventions</td>
<td>Dietary management, pharmacotherapy, strengthening exercises</td>
</tr>
</tbody>
</table>

Guideline

Any of the following treatments is considered medically necessary for severe fecal incontinence when any conservative intervention has failed:

1. Anal sphincter repair
2. Colostomy — member has failed/is not a candidate for medical interventions or surgical sphincter repair (e.g., post-anal repair, sphincteroplasty or total pelvic floor repair, biofeedback pelvic training [check member benefits])
3. Acticon™ Neosphincter artificial bowel sphincter — member is ≥ 18 years of age and has failed/is not a candidate for medical interventions or surgical sphincter repair (e.g., post-anal repair, sphincteroplasty, or total pelvic floor repair)
4. Sacral nerve stimulation (sacral neuromodulation) for chronic fecal incontinence — member has had an inadequate response to conservative treatments and has a weak but structurally intact anal sphincter

Note: A 2–3-week trial with a temporary percutaneous peripheral nerve electrode must be completed before implantation with a permanent implantable pulse generator (e.g., InterStim®) can be considered. Implantation is considered medically necessary when there is a ≥ 50% improvement in incontinence symptoms derived from the temporary percutaneous peripheral nerve stimulation.
Limitations/Exclusions

The Acticon Neosphincter is not considered medically necessary when the above criteria are not met and when its use is contraindicated. (i.e., incontinence complicated by irreversibly obstructed proximal segment of bowel, poor candidacy for surgery or anesthesia, etc.)

The following interventions are not considered medically necessary due to insufficient evidence of therapeutic value:

1. Radiofrequency energy delivery (e.g., Secca Therapy)
2. Perianal electrical stimulation
3. Injectable bulking agents (e.g., Solesta®)
4. Vaginal bowel control (e.g., eclipse system™) (Covered for Medicare members only)
5. Injection of autologous myoblast cells
6. Injection of mesenchymal stem cells
7. Topical estrogen
8. Tibial nerve stimulation
9. Pudendal nerve terminal motor latency
10. Interna® Dermal Regeneration FENIX™ Continence Restoration System

Revision History

7/14/2017 — added Interna® Dermal Regeneration FENIX™ Continence Restoration System as investigational.

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>95972</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable implantable neurostimulator pulse generator</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8684</td>
<td>Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
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</tbody>
</table>
External recharging system for battery (internal) for use with implantable neurostimulator

External recharging system for battery (external) for use with implantable neurostimulator

### Applicable ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>R15.0</td>
<td>Incomplete defecation</td>
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<tr>
<td>R15.1</td>
<td>Fecal smearing</td>
</tr>
<tr>
<td>R15.2</td>
<td>Fecal urgency</td>
</tr>
<tr>
<td>R15.9</td>
<td>Full incontinence of feces</td>
</tr>
</tbody>
</table>

### References


Leung FW. Treatment of fecal incontinence - review of observational studies (OS) and randomized controlled trials (RCT) related to injection of bulking agent into peri-anal tissue. J Interv Gastroenterol 2011; 1(4):202-06


Specialty matched clinical peer review.


Up to Date. Fecal incontinence in adults: Etiology and evaluation. Authors: Kristen M Robson, MD, MBA, FACGAnthony J Lembo, MDSSection Editor:Nicholas J Talley, MD, PhDDeputy Editor:Shilpa Grover, MD, MPH. August 10, 2016.


