



Fecal Incontinence Treatment

| POLICY NUMBER | LAST REVIEW |
|----------------|---------------|
| MG.MM.ME.63bC4 | June 13, 2025 |

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The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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

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| Anal incontinence | Involuntary loss of solid or liquid feces or flatus |
| Severe fecal incontinence | Involuntary loss of solid or liquid feces or flatus on a weekly, or more, frequent basis |
| Conservative medical interventions | Dietary management, pharmacotherapy, strengthening exercises |

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 and 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®) (0377T)
4. Vaginal bowel control (e.g., eclipse system™) (A4563) (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

Procedure Codes

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| 64561 | Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed |
| 64581 | Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement) |
| 64590 | Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling |
| 95972 | 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 |
| L8680 | Implantable neurostimulator electrode, each |
| L8681 | Patient programmer (external) for use with implantable programmable implantable neurostimulator pulse generator |
| L8682 | Implantable neurostimulator radiofrequency receiver |
| L8683 | Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver |
| L8684 | Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and |

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| | bladder management, replacement |
| L8685 | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension |
| L8686 | Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension |
| L8687 | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension |
| L8688 | Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension |
| L8689 | External recharging system for battery (internal) for use with implantable neurostimulator |
| L8695 | External recharging system for battery (external) for use with implantable neurostimulator |

ICD-10 Diagnoses

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| A04.71 | Enterocolitis due to Clostridium difficile, recurrent |
| A04.72 | Enterocolitis due to Clostridium difficile, not specified as recurrent |

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Specialty matched clinical peer review.

Revision History

| Company(ies) | DATE | REVISION |
|------------------------------|---------------|--|
| EmblemHealth | Jun. 13, 2025 | Transferred policy content to individual company branded template |
| EmblemHealth ConnectiCare | May 13, 2022 | ConnectiCare adopts clinical criteria of its parent corporation EmblemHealth |
| ConnectiCare | Jul. 14, 2017 | Added Interna® Dermal Regeneration FENIX™ Continence Restoration System as investigational |