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| MEDICAL POLICY | Fecal Incontinence Treatments (Medicare Only) |
| Effective Date: 7/1/2022  7/1/2022 | Medical Policy Number: 228 |
| | Medical Policy Committee Approved Date: 2/19; 11/19; 8/2020; 08/2021; 11/2021; 5/2022 |
| Medical Officer | Date |

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Aycin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

| Service | Medicare Guidelines |
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| <i>Sacral Nerve Stimulation</i> | Local Coverage Article (LCA): Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017) |
| <i>Manual Pump Enema Systems (e.g. Peristeen® anal irrigation system) and other enema supplies/products (HCPCS A4453, A4459)</i> | Local Coverage Determination (LCD): Bowel Management Devices (L36267) |
| <i>Posterior Tibial Nerve Stimulation (PTNS) for Fecal Incontinence</i> | LCA for Billing and Coding: Posterior Tibial Nerve Stimulation Coverage (A52965) |

In the absence of a Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.), Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (Medicare Managed Care

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*Manual, Ch. 4, §90.5) Therefore, the commercial medical policy, **Fecal Incontinence Treatments (All Lines of Business Except Medicare)**, applies to the following services:*

- Biofeedback
- Bulking agents
- Transanal radiofrequency therapy (Secca procedure)
- Anal sphincter replacement (i.e. Acticon Neosphincter)Vaginal Inserts (e.g., Eclipse™ Vaginal Insert System) (HCPCS A4563)
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BILLING GUIDELINES

See related local coverage articles (LCAs) for billing assistance:

- Local Coverage Article: Bowel Management Devices - Policy Article ([A54516](#))

Additional billing guidelines:

- The Eclipse™ Vaginal Insert system (Pelvalon, Inc.) is an inflatable vaginal insert designed to exert pressure on the rectal vault to treat fecal incontinence. The Eclipse™ system consists of a vaginal insert and a pressure-regulated pump. The insert, consisting of a silicone-covered stainless-steel base and a posteriorly directed balloon, is placed in the vaginal vault and inflated. The balloon is deflated via the pump when the user needs to have a bowel movement. However, the insert must first be fitted in the physician's office and is reported under a CPT code that is all-inclusive. Services rendered in a physician office and billed under a CPT code are not within the jurisdiction of the DME MACs and therefore, the above noted DME LCD and LCA do not address coverage for this device and our Commercial policy criteria are applied.
- The “C” codes listed below are only applicable when billed under the hospital outpatient prospective payment system (OPPS) and they should be submitted in place of HCPCS code A4240.
- CPT codes 90875, 90876, and/or 90901 may be used to bill biofeedback for the treatment of fecal incontinence, which is considered investigational and not covered.
- CPT codes 0587T-0590T and 64566 will deny as not medically necessary when **not** reported with ICD-10 codes that support medical necessity, as determined by the relevant PTNS LCA [A52965](#).
- CPT codes 90912 and 90913 will deny as not medically necessary when billed with ICD-10 codes F98.1, R151, R152, R150, R159 for fecal incontinence.

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- Code A4459 is an all-inclusive code. Separate billing of any of the individual components is not allowed.

CPT/HCPCS CODES

| Medicare Only | |
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| Prior Authorization Required | |
| 64561 | Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed |
| 64581 | Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) |
| 64585 | Revision or removal of peripheral neurostimulator electrode array |
| 64590 | Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling |
| 64595 | Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver |
| A4290 | Sacral nerve stimulation test lead, each |
| C1767 | Generator, neurostimulator (implantable), non-rechargeable |
| C1778 | Lead, neurostimulator (implantable) |
| C1787 | Patient programmer, neurostimulator |
| C1823 | Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads |
| C1897 | Lead, neurostimulator test kit (implantable) |
| L8679 | Implantable neurostimulator, pulse generator, any type |
| L8680 | Implantable neurostimulator electrode, each |
| 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 |
| No PA Required | |
| 0587T | Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve |
| 0588T | Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve |
| 0589T | Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, |

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| | responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters |
| 0590T | Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters |
| 64566 | Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming |
| 90912 | Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient |
| 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) |
| Not Covered | |
| A4453 | Rectal catheter for use with the manual pump-operated enema system, replacement only |
| A4459 | Manual pump enema system, includes balloon, catheter and all accessories, reusable, any type |
| A4563 | Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each |
| L8605 | Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies. |
| Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required. | |
| 46999 | Unlisted procedure, anus |
| 58999 | Unlisted procedure, female genital system (nonobstetrical) |

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

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The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.