Local Coverage Determination (LCD): Bowel Management Devices (L36267)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

## Contractor Information

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<th>CONTRACT NUMBER</th>
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<td>CGS Administrators, LLC</td>
<td>DME MAC</td>
<td>17013 - DME MAC</td>
<td>J-B</td>
<td>Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin</td>
</tr>
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<td>CGS Administrators, LLC</td>
<td>DME MAC</td>
<td>18003 - DME MAC</td>
<td>J-C</td>
<td>Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, North Carolina, New Mexico, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virginia, Virgin Islands, West Virginia</td>
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**LCD Information**

**Document Information**

**LCD ID**
L36267

**LCD Title**
Bowel Management Devices

**Original Effective Date**
For services performed on or after 12/01/2015

**Revision Effective Date**
For services performed on or after 01/01/2017

**Proposed LCD in Comment Period**
N/A

**Revision Ending Date**
N/A

**Source Proposed LCD**
DL36267

**Retirement Date**
N/A

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**Notice Period Start Date**
10/01/2015

**Notice Period End Date**
11/30/2015
CMS National Coverage Policy

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Benefit Category and other statutory requirements are discussed in the related Policy Article NONMEDICAL NECESSITY AND COVERAGE RULES section. Refer to the Policy article for information on these criteria.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:
• The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
• The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
• Refer to the Supplier Manual for additional information on documentation requirements.
• Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Bed Pans (E0275, E0276) are covered for beneficiaries who are bed-confined (see NCD 280.1).

Rectal inserts and related accessories (A4337) will be denied as not reasonable and necessary because they do not meet the medical evidence requirements outlined in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13, §13.7.1.

Electrical continence aids are in the experimental stage of development and there is no valid scientific documentation of their effectiveness and safety; therefore, they are denied as not reasonable and necessary (see NCD 230.15).

Rectal catheters/tubes and related collection systems will be denied as statutorily non-covered (no benefit – see related Policy Article).

Enema systems (gravity and manual pump), codes A4458 and A4459 respectively, will be denied as statutorily non-covered (no benefit – see related Policy Article).

Pulsed irrigation and evacuation systems (E0350, E0352) will be denied as statutorily non-covered (no benefit – see related Policy Article).

Incontinence garments (e.g., briefs, diapers) coded A4520 will be denied as statutorily non-covered (no benefit – see related Policy Article).

Disposable underpads (A4554) and non-disposable (A4553) underpads will be denied as statutorily non-covered (no benefit – see related Policy Article).

Toilet seats, raised toilet seats, toilet seat lift mechanisms, bidets and bidet toilet seats are discussed in the Commodes Local Coverage Determination and related Policy Article.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

Coding Information

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**CPT/HCPCS Codes**

**Group 1 Paragraph:**
The appearance of a code in this section does not necessarily indicate coverage.

**HCPCS MODIFIERS:**
EY - No physician or other licensed health care provider order for this item or service

**HCPCS CODES:**

**Group 1 Codes:**

<table>
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<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
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<tr>
<td>A4335</td>
<td>INCONTINENCE SUPPLY; MISCELLANEOUS</td>
</tr>
<tr>
<td>A4337</td>
<td>INCONTINENCE SUPPLY, RECTAL INSERT, ANY TYPE, EACH</td>
</tr>
<tr>
<td>A4458</td>
<td>ENEMA BAG WITH TUBING, REUSABLE</td>
</tr>
<tr>
<td>A4459</td>
<td>MANUAL PUMP-OPERATED ENEMA SYSTEM, INCLUDES BALLOON, CATHETER AND ALL ACCESSORIES, REUSABLE, ANY TYPE</td>
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<tr>
<td>A4520</td>
<td>INCONTINENCE GARMENT, ANY TYPE, (E.G., BRIEF, DIAPER), EACH</td>
</tr>
<tr>
<td>A4553</td>
<td>NON-DISPOSABLE UNDERPADS, ALL SIZES</td>
</tr>
<tr>
<td>A4554</td>
<td>DISPOSABLE UNDERPADS, ALL SIZES</td>
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<tr>
<td>A9270</td>
<td>NON-COVERED ITEM OR SERVICE</td>
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<tr>
<td>E0275</td>
<td>BED PAN, STANDARD, METAL OR PLASTIC</td>
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<tr>
<td>E0276</td>
<td>BED PAN, FRACTURE, METAL OR PLASTIC</td>
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<tr>
<td>E0350</td>
<td>CONTROL UNIT FOR ELECTRONIC BOWEL IRRIGATION/EVACUATION SYSTEM</td>
</tr>
<tr>
<td>E0352</td>
<td>DISPOSABLE PACK (WATER RESERVOIR BAG, SPECULUM, VALVING MECHANISM AND COLLECTION BAG/BOX) FOR USE WITH THE ELECTRONIC BOWEL IRRIGATION/EVACUATION SYSTEM</td>
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**ICD-10 Codes that Support Medical Necessity**

N/A

**ICD-10 Codes that DO NOT Support Medical Necessity**

**Group 1 Paragraph:**

Not Applicable

**Group 1 Codes:** N/A

**Additional ICD-10 Information**

N/A
**General Information**

**Associated Information**

**DOCUMENTATION REQUIREMENTS**

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

**GENERAL DOCUMENTATION REQUIREMENTS**

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

**POLICY SPECIFIC DOCUMENTATION REQUIREMENTS**

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

**Miscellaneous**

**Appendices**

**Utilization Guidelines**

Refer to Coverage Indications, Limitations and/or Medical Necessity

**Sources of Information**

N/A

**Bibliography**
## Revision History Information

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<th>REVISION HISTORY DATE</th>
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<th>REVISION HISTORY EXPLANATION</th>
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<td>01/01/2017</td>
<td>R7</td>
<td>No changes have been made to this LCD.</td>
<td>Other</td>
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<td><em>04/05/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</em></td>
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<tr>
<td>07/01/2016</td>
<td>R5</td>
<td>Revision Effective Date 07/01/2016 COVERAGE INDICATIONS, INDICATIONS,</td>
<td>Provider</td>
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<td>R4</td>
<td>Revision Effective Date 07/01/2016</td>
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<td>Coverage indications, indications, limitations and/or medical necessity: Added: Vaginal inserts and accessories information (Effective date 02/12/2015)</td>
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<td>Hcpcs modifiers: Deleted: GA, GZ, GY modifiers documentation requirements: Revised: Standard documentation language to Orders, revise Proof of delivery instructions, and add Correct coding instructions (Effective date 04/28/2016)</td>
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<td>07/01/2016</td>
<td>R3</td>
<td>Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.</td>
<td>Change in Assigned States or Affiliated Contract Numbers</td>
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<td>Coverage indications, indications, limitations and/or medical necessity: Replaced: Miscellaneous HCPCS Code A4335 with new code A4337</td>
<td>Revisions Due To CPT/HCPCS Code Changes</td>
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<td>Hcpcs codes: Added: HCPCS Code A4337</td>
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<td>12/01/2015 - Draft LCD promoted to final</td>
<td>Other (Draft LCD promoted to final)</td>
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END OF LOCAL COVERAGE DETERMINATION
Per the Code of Federal Regulations, 42 C.F.R § 426.325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.
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**Article Information**

**General Information**

**Article ID**
A54516

**Original Article Effective Date**
10/01/2015

**Article Title**
Bowel Management Devices - Policy Article

**Revision Effective Date**
01/01/2019

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NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

In order for any item to be eligible for coverage under Medicare, the item must be eligible for inclusion into one of the existing coverage Benefit Categories. Rectal inserts and electrical incontinence aids are covered under the Prosthetic Devices benefit (Social Security Act §1861(s)(9)). Bed pans are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary’s equipment to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Many bowel management devices (see bulleted list below, not all inclusive) fail one or more of the relevant requirements in §1861(n) of the Act and are thus statutorily excluded from coverage (see the CMS Nation Coverage Determinations Manual (Internet-only Manual 100-03) Chapter 1, Part 4, §280.1):

- Disposable Sheets and Bags (A4335) – Deny – Non-reusable disposable supplies
- Incontinence Pads (A4553 and A4554) – Deny – Non-reusable supply; Hygienic item
Diapers (A4520) - Deny – Non-reusable supply; Hygienic item

Manual pump enema systems (e.g., Peristeen® - Coloplast, Minneapolis, MN) or gravity-administered enema systems do not meet the Durable Medical Equipment (DME) benefit because these devices do not meet the requirement of durability. In addition, these devices do not meet the Prosthetic Benefit because they do not replace a non-functioning internal body organ.

Rectal catheters/tubes and related collection systems do not meet the Durable Medical Equipment (DME) benefit because these devices do not meet the requirement of durability. In addition, these devices do not meet the Prosthetic Benefit because they do not replace a non-functioning internal body organ.

Pulsed irrigation and evacuation devices (PIE* – P.I.E. Medical Inc., Buford, GA) do not meet the DME benefit because they are considered institutional equipment.

Vaginal inserts and related accessories (Eclipse™ Vaginal Insert system - Pelvalon, Inc) for the treatment of fecal incontinence are not DME MAC jurisdiction. Claims for vaginal inserts and related accessories (A4563 - RECTAL CONTROL SYSTEM FOR VAGINAL INSERTION, FOR LONG TERM USE, INCLUDES PUMP AND ALL SUPPLIES AND ACCESSORIES, ANY TYPE EACH) submitted to the DME MACs will be rejected as wrong jurisdiction.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

CODING GUIDELINES

Rectal inserts are prosthetic devices constructed of rubber, latex, silicone or other similar material and act as a barrier to the passage of fecal matter through the rectum. Use code A4337 (INCONTINENCE SUPPLY, RECTAL INSERT, ANY TYPE, EACH) for this item. Code A4337 includes the insert and any associated supplies or accessories for insertion and maintenance of the device.

Rectal catheters/tubes and related collection systems are products designed to be inserted into the rectum to collect fecal material. They also serve to assist in protection of perianal skin integrity in the patient with fluid and semi-fluid waste.

An electrical continence aid is a prosthetic device consisting of a plastic plug, molded into the shape of the patient's anal canal, which contains two implanted electrodes that are connected by a wire to a small portable generator. An electrical current is produced which stimulates the anal musculature to cause a contraction sufficient to hold the plug in while allowing the patient to ambulate without incontinence.

Codes A4458 (ENEMA BAG WITH TUBING, REUSABLE) and code A4459 (MANUAL PUMP ENEMA SYSTEM, INCLUDES BALLOON, CATHETER AND ALL ACCESSORIES, REUSABLE, ANY TYPE) describe devices used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or simply as a method of bowel management. An enema system consists of an irrigation fluid holding chamber and a rectal catheter (with or without an inflatable balloon). Fluid is instilled either via gravity or a manual pump.
The Peristeen® transanal irrigation system is a device used to empty the lower bowel and to prevent chronic constipation and fecal incontinence or simply as a method of bowel management. The system consists of an enema bag, a rectal catheter with an inflatable balloon and a pump. Effective for claims with dates of service on or after January 1, 2015, the correct code to bill is A4459 (MANUAL PUMP ENEMA SYSTEM, INCLUDES BALLOON, CATHETER AND ALL ACCESSORIES, REUSABLE, ANY TYPE).

Code A4459 is an all-inclusive code. Separate billing of any of the individual components is not allowed. For billing refills of disposable supplies such as rectal catheters, HCPCS code A9900 (MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE) must be used.

Code E0350 describes a colorectal irrigation system that consists of an irrigation fluid holding chamber, a rectal catheter with an inflatable balloon and an electric pump. Irrigation fluid is administered in a pulsatile manner to hydrate stool to a semi-liquid form and allow the liquefied stool to evacuate. Code E0352 describes all disposable supplies and accessories used with code E0350 including, but not limited to, a water reservoir, speculum, valve mechanism and collection bag or box.

Codes E0275 (BED PAN, STANDARD, METAL OR PLASTIC) and E0276 (BED PAN, FRACTURE, METAL OR PLASTIC) describe a shallow vessel placed under a bedridden patient to collect feces and urine. To meet Medicare coverage and DME benefit requirements, they must be durable. Disposable bed pans must be billed using code A9270 (NONCOVERED ITEM OR SERVICE).

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

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**Coding Information**

**Bill Type Codes:**
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**CPT/HCPCS Codes**
## Revision History Information

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<th>REVISION HISTORY NUMBER</th>
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| 01/01/2019            | R8                      | Revision Effective Date: 01/01/2019  
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  
Added: HCPCS code A4563 for vaginal inserts  

01/31/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination. |
| 01/01/2017            | R7                      | Revision Effective Date: 01/01/2017  
CODING GUIDELINES:  
Added: Peristeen® coding guidelines  

04/05/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination. |
| 01/01/2017            | R6                      | Revision Effective Date: 01/01/2017  
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  
Added: HCPCS Codes A4553 to Statutorily excluded from coverage list  
Added: Policy Specific Documentation Requirements  
RELATED LOCAL COVERAGE DOCUMENTS:  
Added: LCD-related Standard Documentation Requirements Language Article |
| 07/01/2016            | R5                      | Revision Effective Date: 07/01/2016  
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  
Added: Jurisdictional statement for vaginal inserts (Effective date 02/12/2015)  
CODING GUIDELINES:  
Deleted: Coding guideline definition of vaginal insert (Effective date 02/12/2015) |
| 07/01/2016            | R4                      | Revision Effective Date: 07/01/2016 |
### Associated Documents

**Related Local Coverage Document(s)**

Article(s)

- **A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs**

Area(s)

- **L36267 - Bowel Management Devices**

**Related National Coverage Document(s)**

N/A

**Statutory Requirements URL(s)**

N/A

**Rules and Regulations URL(s)**

N/A

**CMS Manual Explanations URL(s)**

N/A

**Other URL(s)**

N/A

**Public Version(s)**

Updated on 01/25/2019 with effective dates 01/01/2019 - N/A

Updated on 03/28/2018 with effective dates 01/01/2017 - N/A

Updated on 03/09/2017 with effective dates 01/01/2017 - N/A

**Keywords**

N/A