

Bowel Management-Fecal Incontinence Devices

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

Members benefit documents will supersede this policy

National Coverage Determination Policy	(Internet-Only Manual 100-03), Chapter 1, Part 4, §230.15, and §280.1. NCD 280.1
Local Coverage Determination Policy	J-B/C
Effective Date	For services performed on or after 12/01/15
Review/Revisions	01/2019, 10/18, 5/2018, 04/01/17, 09/22/16, 07/01/16
The Health Plan	<p>Medicare and Commercial Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents.</p> <p>West Virginia Medicaid. Please see The Health Plan DME POS Authorization and Compensation Guide.</p>

DESCRIPTION:

It is designed to safely and effectively contain and divert fecal matter, protect patients' wounds from fecal contamination and reduce both the risk of skin breakdown and spread of infection.

COVERAGE GUIDELINES

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

NONCOVERAGE STATEMENT

Rectal inserts and related accessories (**A4335, 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 investigational and experimental. (see NCD 230.15).

Rectal catheters/tubes and related collection systems will be denied as they do not meet the durability requirement, nor do they replace a non-functioning internal body part.

Enema systems (gravity and manual pump), codes **A4458** and **A4459** respectively, will be denied as they do not meet the requirement for durability, nor do they replace a non-functioning body part. They are considered over the counter for commercial and self-funded plans. Example: (Peristeen® - Coloplast, Minneapolis, MN).

Pulsed irrigation and evacuation systems (**E0350, E0352**) will be denied as they are considered institutional equipment. Example: (PIE* – P.I.E. Medical Inc., Buford, GA).

Incontinence garments (e.g., briefs, diapers) coded **A4520** will be denied as statutorily non-covered for Medicare plans. They are considered over the counter for commercial and self-funded plans. **May be covered under Medicaid Benefit. See THP DME POS Authorization and Compensation Guide.**

Disposable underpads (**A4554**) and non-disposable underpads (**A4553**) will be denied as statutorily non-covered for Medicare plans. They are considered over the counter for commercial and self-funded plans. **May be covered under Medicaid Benefit. See THP DME POS Authorization and Compensation Guide.**

See Commode Policy for guidelines on toilet seats, raised toilet seats, toilet seat lift mechanisms, bidets and bidet toilet seats.

The Eclipse™ Vaginal Insert system (Pelvalon, Inc.) is an inflatable vaginal insert designed to exert pressure on the rectal vault to treat fecal incontinence. FDA approval for marketing under this indication was granted on February 12, 2015. According to the manufacturer, 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.

The insert must first be fitted in the physician's office. As determined by The Medicare DME MACs, this procedure is billed under a CPT code **A4335**, it is all-inclusive. **Items provided as part**

of that service are considered incident to the service and are not separately billable as Durable Medical Equipment to The Health Plan.

REPAIR, REPLACEMENT, AND REASONABLE USEFUL LIFETIME

Repairs are not covered for bedpans.

See The Health Plan DME POS Authorization and Compensation Guide for replacements.

CODING INFORMATION

HCPCS MODIFIERS:

EY	No physician or other licensed health care provider order for this item or service
GA	Waiver of liability statement issued as required by payer policy, individual case
GY	Item or service statutorily excluded or does not meet the definition of any Medicare Benefit
GZ	Item or service expected to be denied as not reasonable and necessary

HCPCS CODES:

A4335	INCONTINENCE SUPPLY; MISCELLANEOUS
A4337	INCONTINENCE SUPPLY,RECTAL INSERT, ANY TYPE
A4458	ENEMA BAG WITH TUBING, REUSABLE
A4459	MANUAL PUMP-OPERATED ENEMA SYSTEM, INCLUDES BALLOON CATHETER AND ALL ACCESSORIES, REUSABLE, ANY TYPE
A4520	INCONTINENCE GARMENT, ANY TYPE, (E.G. BRIEF, DIAPER), EACH
A4553	NON-DISPOSABLE UNDERPADS, ALL SIZES
A4554	DISPOSABLE UNDERPADS, ALL SIZES
A9270	NON-COVERED ITEM OR SERVICE
E0275	BED PAN, STANDARD, METAL OR PLASTIC
E0276	BED PAN, FRACTURE, METAL OR PLASTIC
E0350	CONTROL UNIT FOR ELECTRONIC BOWEL IRRIGATION/EVACUATION SYSTEM

E0352	DISPOSABLE PACK (WATER RESERVOIR BAG, SPECULUM, VALVING MECHANISM AND COLLECTION BAG/BOX) FOR USE WITH THE ELECTRONIC BOWEL IRRIGATION/EVACUATION SYSTEM
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There are no ICD-10 codes that support medical necessity for most plan designs

DOCUMENTATION REQUIREMENTS

For West Virginia Medicaid the diagnosis code that justifies the need for these items must be provided at time of precertification and included on the claim.

GA, GY, AND GZ MODIFIERS:

For enema systems (A4458 and A4459), incontinence garments (A4520) and disposable underpads (A4554), the GY modifier must be added to the code, and the GA or GZ modifier must not be used. (Refer to the related Policy Article for additional information.)

If all of the criteria in the Coverage Indications, Limitations and/or Medical Necessity section have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter a GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or a GZ modifier if they have not obtained a valid ABN.

Claim lines billed without a GA, GY or GZ modifier will be rejected as missing information.

Miscellaneous

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

Appendices

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-08

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 A4335 (INCONTINENCE SUPPLY, MISCELLANEOUS) for this item. Code A4335 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 via either gravity or a manual pump.

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, valving 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 bedpans must be billed using code A9270 (NONCOVERED ITEM OR SERVICE).

Code A4335 is a miscellaneous code. Items billed with a miscellaneous HCPCS code require the following documentation to be submitted with the claim:

- Description of the item or service
- Manufacturer name
- Product name and number

Miscellaneous HCPCS codes billed without this information will be denied for missing documentation and will need to be resubmitted with the missing information.

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

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LINKS AND SOURCES

CMS.gov. Centers for Medicare and Medicaid Services. Local Coverage Determination LCD (L36267). Bowel management Devices (L36267). Article (A54516). Last accessed 10/25/18. Retrieved from: <https://www.cms.gov/medicare/coverage/determinationprocess/LCDs.html>

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West Virginia Bureau of Medical Services

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Noridian PDAC Medicare Pricing, Data Analysis, and Coding. Correct Coding Eclipse Vaginal Insert System (Pelvalon, Inc.). Last Accessed 10/25/18. Retrieved from: https://www.dmepdac.com/resources/articles/2016/08_22_16.html

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