

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

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 -	DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota
CGS Administrators, LLC	DME MAC	18003 -	DME MAC J-C	
Noridian Healthcare Solutions, LLC	DME MAC	16013 -	DME MAC J-A	
Noridian Healthcare Solutions, LLC	DME MAC	19003 -	DME MAC J-D	

LCD Information

Document Information

LCD ID L36267	Original Effective Date For services performed on or after 12/01/2015
LCD Title Bowel Management Devices	Revision Effective Date For services performed on or after 01/01/2017
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	Retirement Date N/A
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	Notice Period End Date 11/30/2015
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CMS National Coverage Policy National Coverage Determination Manual (Internet-Only Manual 100-03), Chapter 1, Part 4, §230.15, and §280.1.	

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.

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:

A4335 INCONTINENCE SUPPLY; MISCELLANEOUS

A4337 INCONTINENCE SUPPLY, RECTAL INSERT, ANY TYPE, EACH

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

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: Not Applicable

Group 1 Codes: N/A

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph: Not Applicable

Group 1 Codes: N/A

ICD-10 Additional Information

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[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 and Basis for Decision

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2017	R6	<p>Revision Effective Date: 01/01/2017 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements Added: Denial language for A4553 HCPCS CODES: Added: HCPCS Code A4553 DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Deleted: Sources of Information Removed: Information under Miscellaneous and Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article</p>	<ul style="list-style-type: none"> Provider Education/Guidance Revisions Due To CPT/HCPCS Code Changes
07/01/2016	R5	<p>Revision Effective Date 07/01/2016 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Coverage statement for vaginal inserts and related accessories; they are not DME MAC Jurisdiction (Effective date 02/12/2015) SOURCES OF INFORMATION AND BASIS FOR DECISION: Removed: Links</p>	<ul style="list-style-type: none"> Provider Education/Guidance Other (Vaginal Inserts and related accessories are not DME MAC Jurisdiction)
07/01/2016	R4	<p>Revision Effective Date 07/01/2016 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Vaginal inserts and accessories information (Effective date 02/12/2015) 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) POLICY SPECIFIC DOCUMENTATION REQUIREMENTS Deleted: GA, GZ, GY modifiers section</p>	<ul style="list-style-type: none"> Provider Education/Guidance
07/01/2016	R3	<p>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.</p>	<ul style="list-style-type: none"> Change in Assigned States or Affiliated Contract Numbers
01/01/2016	R2	<p>Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Replaced: Miscellaneous HCPCS Code A4335 with new code A4337 HCPCS CODES:</p>	<ul style="list-style-type: none"> Provider Education/Guidance Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
12/01/2015	R1	Added: HCPCS Code A4337 DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015) 12/01/2015 - Draft LCD promoted to final	<ul style="list-style-type: none"> Other (Draft LCD promoted to final)

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) [A54516 - Bowel Management Devices - Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

Related National Coverage Documents N/A

Public Version(s) Updated on 03/09/2017 with effective dates 01/01/2017 - N/A [Updated on 11/03/2016 with effective dates 07/01/2016 - 12/31/2016](#) [Updated on 08/03/2016 with effective dates 07/01/2016 - N/A](#) [Updated on 06/07/2016 with effective dates 07/01/2016 - N/A](#) [Updated on 02/26/2016 with effective dates 01/01/2016 - 06/30/2016](#) Some older versions have been archived. Please visit the [MCD Archive Site](#) to retrieve them. [Back to Top](#)

Keywords

N/A Read the [LCD Disclaimer](#) [Back to Top](#)

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.

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

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Contractor Information

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CGS Administrators, LLC	DME MAC	17013 -	DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota
CGS Administrators, LLC	DME MAC	18003 -	DME MAC J-C	
Noridian Healthcare Solutions, LLC	DME MAC	16013 -	DME MAC J-A	
Noridian Healthcare Solutions, LLC	DME MAC	19003 -	DME MAC J-D	

Article Information

General Information

Article ID

A54516

Original Article Effective Date

10/01/2015

Article Title

Bowel Management Devices - Policy Article

Revision Effective Date

01/01/2017

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Revision Ending Date

N/A

Retirement Date

N/A

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Article Guidance

Article Text:**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 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.

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. [Back to Top](#)

[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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article 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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A

ICD-10 Codes that are Covered N/A

ICD-10 Codes that are Not Covered N/A

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[Revision History Information](#)

Revision History Date	Revision History Number	Revision History Explanation
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

Revision History Date	Revision History Number	Revision History Explanation
07/01/2016	R5	Added: Policy Specific Documentation Requirements RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article 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) Revision Effective Date: 07/01/2016
07/01/2016	R4	CODING GUIDELINES: Added: Coding guideline definition of vaginal insert (Effective date 02/12/2015) Effective July 1, 2016 oversight for DME MAC Articles 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 Articles. Revision Effective Date: 01/01/2016
07/01/2016	R3	CODING GUIDELINES: Replaced: Miscellaneous HCPCS Code A4335 with new code A4337 10/01/2015 - Draft Policy Article promoted to final
01/01/2016	R2	
12/01/2015	R1	

[Back to Top](#) **Related Local Coverage Document(s)** Article(s) [A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#) LCD(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

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[Keywords](#)

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