

Local Coverage Determination (LCD): Ostomy Supplies (L33828)

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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
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

LCD Information

Document Information

LCD ID

L33828

Original Effective Date

For services performed on or after 10/01/2015

LCD Title

Ostomy Supplies

Revision Effective Date

For services performed on or after 01/01/2020

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

N/A

Retirement Date

N/A

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N/A

Notice Period End Date

N/A

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CMS National Coverage Policy

None

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.

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.

The quantity of ostomy supplies needed by a beneficiary is determined primarily by the type of ostomy, its location, its construction, and the condition of the skin surface surrounding the stoma. There will be variation according to individual beneficiary need and their needs may vary over time. The table below lists the maximum number of items/units of service that are usually reasonable and necessary. The actual quantity needed for a particular beneficiary may be more or less than the amount listed depending on the factors that affect the frequency of barrier and pouch change.

The explanation for use of a greater quantity of supplies than the amounts listed must be clearly documented in the beneficiary’s medical record. If adequate documentation is not provided when requested, the excess quantities will be denied as not reasonable and necessary.

USUAL MAXIMUM QUANTITY OF SUPPLIES:

Code	# per Month
A4357	2
A4362	20
A4364	4
A4367	1
A4369	2
A4377	10
A4381	10
A4397	4
A4402	4
A4404	10

A4405	4
A4406	4
A4414	20
A4415	20
A4416	60
A4417	60
A4418	60
A4419	60
A4420	60
A4423	60
A4424	20
A4425	20
A4426	20
A4427	20
A4429	20
A4431	20
A4432	20
A4433	20
A4434	20

A4450	40
A4452	40
A5051	60
A5052	60
A5053	60
A5054	60
A5055	31
A5056	40
A5057	40
A5061	20
A5062	20
A5063	20
A5071	20
A5072	20
A5073	20
A5081	31
A5082	1
A5083	150
A5093	10

A5121	20
A5122	20
A5126	20
A5131	1
A6216	60

Code	# per 6 Months
A4361	3
A4371	10
A4398	2
A4399	2
A4455	16
A5102	2
A5120	150

When a liquid barrier is necessary, either liquid or spray (A4369) or individual wipes or swabs (A5120) are appropriate. The use of both is not reasonable and necessary.

Beneficiaries with continent stomas may use the following means to prevent/manage drainage: stoma cap (A5055), stoma plug (A5081), stoma absorptive cover (A5083) or gauze pads (A6216). No more than one of these types of supply would be reasonable and necessary on a given day.

Beneficiaries with urinary ostomies may use either a bag (A4357) or bottle (A5102) for drainage at night. It is not reasonable and necessary to have both.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) 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.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioners that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a one (1) -month supply at a time for a beneficiary

in a nursing facility and a three (3) -month supply for a beneficiary at home.

For information on tracheostomy supplies, see the Tracheostomy Care Supplies policy.

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

AU - Item furnished in conjunction with a urological, ostomy or tracheostomy supply.

EY - No physician or other licensed health care provider order for this item or service.

HCPCS CODES:

Group 1 Codes:

CODE	DESCRIPTION
A4331	EXTENSION DRAINAGE TUBING, ANY TYPE, ANY LENGTH, WITH CONNECTOR/ADAPTOR, FOR USE WITH URINARY LEG BAG OR UROSTOMY POUCH, EACH
A4357	BEDSIDE DRAINAGE BAG, DAY OR NIGHT, WITH OR WITHOUT ANTI-REFLUX DEVICE, WITH OR WITHOUT TUBE, EACH
A4361	OSTOMY FACEPLATE, EACH
A4362	SKIN BARRIER; SOLID, 4 X 4 OR EQUIVALENT; EACH
A4363	OSTOMY CLAMP, ANY TYPE, REPLACEMENT ONLY, EACH
A4364	ADHESIVE, LIQUID OR EQUAL, ANY TYPE, PER OZ

CODE	DESCRIPTION
A4366	OSTOMY VENT, ANY TYPE, EACH
A4367	OSTOMY BELT, EACH
A4368	OSTOMY FILTER, ANY TYPE, EACH
A4369	OSTOMY SKIN BARRIER, LIQUID (SPRAY, BRUSH, ETC.), PER OZ
A4371	OSTOMY SKIN BARRIER, POWDER, PER OZ
A4372	OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, STANDARD WEAR, WITH BUILT-IN CONVEXITY, EACH
A4373	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITH BUILT-IN CONVEXITY, ANY SIZE, EACH
A4375	OSTOMY POUCH, DRAINABLE, WITH FACEPLATE ATTACHED, PLASTIC, EACH
A4376	OSTOMY POUCH, DRAINABLE, WITH FACEPLATE ATTACHED, RUBBER, EACH
A4377	OSTOMY POUCH, DRAINABLE, FOR USE ON FACEPLATE, PLASTIC, EACH
A4378	OSTOMY POUCH, DRAINABLE, FOR USE ON FACEPLATE, RUBBER, EACH
A4379	OSTOMY POUCH, URINARY, WITH FACEPLATE ATTACHED, PLASTIC, EACH
A4380	OSTOMY POUCH, URINARY, WITH FACEPLATE ATTACHED, RUBBER, EACH
A4381	OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, PLASTIC, EACH
A4382	OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, HEAVY PLASTIC, EACH
A4383	OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, RUBBER, EACH
A4384	OSTOMY FACEPLATE EQUIVALENT, SILICONE RING, EACH
A4385	OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, EACH
A4387	OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4388	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, (1 PIECE), EACH
A4389	OSTOMY POUCH, DRAINABLE, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4390	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4391	OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED (1 PIECE), EACH
A4392	OSTOMY POUCH, URINARY, WITH STANDARD WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4393	OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH

CODE	DESCRIPTION
A4394	OSTOMY DEODORANT, WITH OR WITHOUT LUBRICANT, FOR USE IN OSTOMY POUCH, PER FLUID OUNCE
A4395	OSTOMY DEODORANT FOR USE IN OSTOMY POUCH, SOLID, PER TABLET
A4396	OSTOMY BELT WITH PERISTOMAL HERNIA SUPPORT
A4397	IRRIGATION SUPPLY; SLEEVE, EACH
A4398	OSTOMY IRRIGATION SUPPLY; BAG, EACH
A4399	OSTOMY IRRIGATION SUPPLY; CONE/CATHETER, WITH OR WITHOUT BRUSH
A4402	LUBRICANT, PER OUNCE
A4404	OSTOMY RING, EACH
A4405	OSTOMY SKIN BARRIER, NON-PECTIN BASED, PASTE, PER OUNCE
A4406	OSTOMY SKIN BARRIER, PECTIN-BASED, PASTE, PER OUNCE
A4407	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE, OR ACCORDION), EXTENDED WEAR, WITH BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4408	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITH BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4409	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4410	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4411	OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, EXTENDED WEAR, WITH BUILT-IN CONVEXITY, EACH
A4412	OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITHOUT FILTER, EACH
A4413	OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITH FILTER, EACH
A4414	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITHOUT BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4415	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITHOUT BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4416	OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4417	OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FILTER (1 PIECE), EACH
A4418	OSTOMY POUCH, CLOSED; WITHOUT BARRIER ATTACHED, WITH FILTER (1 PIECE),

CODE	DESCRIPTION
	EACH
A4419	OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FILTER (2 PIECE), EACH
A4420	OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE), EACH
A4421	OSTOMY SUPPLY; MISCELLANEOUS
A4422	OSTOMY ABSORBENT MATERIAL (SHEET/PAD/CRYSTAL PACKET) FOR USE IN OSTOMY POUCH TO THICKEN LIQUID STOMAL OUTPUT, EACH
A4423	OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FILTER (2 PIECE), EACH
A4424	OSTOMY POUCH, DRAINABLE, WITH BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4425	OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FILTER (2 PIECE SYSTEM), EACH
A4426	OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE SYSTEM), EACH
A4427	OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FILTER (2 PIECE SYSTEM), EACH
A4428	OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4429	OSTOMY POUCH, URINARY, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4430	OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4431	OSTOMY POUCH, URINARY; WITH BARRIER ATTACHED, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4432	OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FAUCET-TYPE TAP WITH VALVE (2 PIECE), EACH
A4433	OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE), EACH
A4434	OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FAUCET-TYPE TAP WITH VALVE (2 PIECE), EACH
A4435	OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, WITH EXTENDED WEAR BARRIER (ONE-PIECE SYSTEM), WITH OR WITHOUT FILTER, EACH
A4450	TAPE, NON-WATERPROOF, PER 18 SQUARE INCHES
A4452	TAPE, WATERPROOF, PER 18 SQUARE INCHES

CODE	DESCRIPTION
A4455	ADHESIVE REMOVER OR SOLVENT (FOR TAPE, CEMENT OR OTHER ADHESIVE), PER OUNCE
A4456	ADHESIVE REMOVER, WIPES, ANY TYPE, EACH
A5051	OSTOMY POUCH, CLOSED; WITH BARRIER ATTACHED (1 PIECE), EACH
A5052	OSTOMY POUCH, CLOSED; WITHOUT BARRIER ATTACHED (1 PIECE), EACH
A5053	OSTOMY POUCH, CLOSED; FOR USE ON FACEPLATE, EACH
A5054	OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH FLANGE (2 PIECE), EACH
A5055	STOMA CAP
A5056	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH FILTER, (1 PIECE), EACH
A5057	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT IN CONVEXITY, WITH FILTER, (1 PIECE), EACH
A5061	OSTOMY POUCH, DRAINABLE; WITH BARRIER ATTACHED, (1 PIECE), EACH
A5062	OSTOMY POUCH, DRAINABLE; WITHOUT BARRIER ATTACHED (1 PIECE), EACH
A5063	OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH FLANGE (2 PIECE SYSTEM), EACH
A5071	OSTOMY POUCH, URINARY; WITH BARRIER ATTACHED (1 PIECE), EACH
A5072	OSTOMY POUCH, URINARY; WITHOUT BARRIER ATTACHED (1 PIECE), EACH
A5073	OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH FLANGE (2 PIECE), EACH
A5081	STOMA PLUG OR SEAL, ANY TYPE
A5082	CONTINENT DEVICE; CATHETER FOR CONTINENT STOMA
A5083	CONTINENT DEVICE, STOMA ABSORPTIVE COVER FOR CONTINENT STOMA
A5093	OSTOMY ACCESSORY; CONVEX INSERT
A5102	BEDSIDE DRAINAGE BOTTLE WITH OR WITHOUT TUBING, RIGID OR EXPANDABLE, EACH
A5120	SKIN BARRIER, WIPES OR SWABS, EACH
A5121	SKIN BARRIER; SOLID, 6 X 6 OR EQUIVALENT, EACH
A5122	SKIN BARRIER; SOLID, 8 X 8 OR EQUIVALENT, EACH
A5126	ADHESIVE OR NON-ADHESIVE; DISK OR FOAM PAD
A5131	APPLIANCE CLEANER, INCONTINENCE AND OSTOMY APPLIANCES, PER 16 OZ.
A6216	GAUZE, NON-IMPREGNATED, NON-STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING
A9270	NON-COVERED ITEM OR SERVICE

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:

- SWO
- 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

Reserved for future use.

Bibliography

NA

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R4	<p>Revision Effective Date: 01/01/2020</p> <p>GENERAL: Revised: Order information as a result of Final Rule 1713</p> <p>REFILL REQUIREMENTS: Revised: "ordering physicians" to "treating practitioners"</p> <p>CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information"</p> <p>DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "treating practitioner's"</p> <p>GENERAL DOCUMENTATION REQUIREMENTS: Revised: "Prescriptions (orders)" to "SWO"</p> <p><i>02/20/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713.</i></p>	<ul style="list-style-type: none">• Provider Education/Guidance• Other
01/01/2017	R3	<p>Revision History Effective Date: 01/01/2017:</p> <p>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 Revised: Refill Requirements</p> <p>DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language</p>	<ul style="list-style-type: none">• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>Added: General Documentation Requirements</p> <p>Added: New reference language and directions to Standard Documentation Requirements</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</p> <p>Removed: Standard Documentation Language</p> <p>Added: Direction to Standard Documentation Requirements</p> <p>Removed: Supplier Manual reference from Miscellaneous</p> <p>Removed: PIM reference from Appendices</p> <p>RELATED LOCAL COVERAGE DOCUMENTS:</p> <p>Added: LCD-related Standard Documentation Requirements article</p>	
07/01/2016	R2	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.	<ul style="list-style-type: none"> Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	<p>Revsion History Effective Date: 08/01/2015</p> <p>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:</p> <p>Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility</p> <p>DOCUMENTATION REQUIREMENTS:</p> <p>Removed: ICD-9 references</p> <p>Revised: Standard Documentation Language to add who can enter date of delivery date on the POD (Note: The effective date above is not applicable to this section. These revised and added requirements are existing Medicare requirements which are now included in the LCD for easy reference)</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</p> <p>Added: Language for HCPCS codes A4450, A4452 and A5120 when submitted without correct modifier</p>	<ul style="list-style-type: none"> Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A52487 - Ostomy Supplies - Policy Article

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

Related National Coverage Documents

N/A

Public Version(s)

Updated on 02/14/2020 with effective dates 01/01/2020 - N/A

Updated on 04/28/2017 with effective dates 01/01/2017 - 12/31/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A

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: Ostomy Supplies - Policy Article (A52487)

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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
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

Article Information

General Information

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Ostomy Supplies - Policy Article

Retirement Date

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Article Type

Article

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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 Section 1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Ostomy supplies are covered under the Prosthetic Device benefit (Social Security Act Section 1861(s)(8)). 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.

Ostomy supplies are covered for use on a beneficiary with a surgically created opening (stoma) to divert urine, or fecal contents outside the body. Ostomy supplies are appropriately used for colostomies, ileostomies or urinary ostomies (see covered diagnosis codes below.) Use for other conditions will be denied as noncovered.

A pouch cover should be coded A9270 and will be denied as a noncovered item.

Ostomy supplies are not separately payable when a beneficiary is in a covered home health episode. Ostomy supplies must be provided by the home health agency and payment is included in the home health Medicare payment rate. It is not appropriate to bill these to the DME MAC.

Claims for tape and adhesive (A4450, A4452, A5120) that are billed without an AU modifier or another modifier indicating coverage under a different policy will be rejected as missing information.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

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.

For quantities of supplies that exceed the usual maximum amount, there must be information in the medical record that explains the need for the increased amount. This information must be available upon request.

Claims lines for A4450, A4452 and A5120 billed without AU modifier will be rejected as missing information.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered,

therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. Once initial medical need is established, ongoing need for ostomy supplies is assumed to be met. There is no requirement for further documentation of continued medical need as long as the beneficiary continues to meet the Prosthetic Devices benefit.

CODING GUIDELINES

BARRIERS:

A solid barrier (wafer) is an interface between the beneficiary's skin and the pouching system, has measurable thickness and has an adhesive property. Barriers may be integrated into a "1 piece" pouch, they may be manufactured with a flange and be part of a "2 piece" pouch system (skin barrier with flange, e.g., A4414), or they may be used independently (e.g., A4362), usually with a pouch that does not have its own integral skin barrier. An extended wear barrier (e.g., A4409) is a pectin-based barrier with special additives which achieve a stronger adhesive seal, resist breakdown by urine or bowel effluent, permit longer wear times between changes, and normal wear times for those who cannot achieve them with standard barriers. There are distinct codes for extended wear compared to standard wear barriers.

A barrier with built-in convexity (e.g., A4407 or A4411) is one in which an outward curve is usually achieved with plastic embedded in the barrier, allowing better protrusion of the stoma and adherence to the skin. There are distinct codes for barriers with built-in convexity compared to flat barriers.

Ostomy skin barriers greater than 4x4 inches (e.g., A4408) refer to the size of the skin barriers themselves, and not to the area of any surrounding tape.

FACEPLATES:

A faceplate is a solid interface between the beneficiary's skin and the pouch. It is usually made of plastic, rubber or encased metal. It does not have an adhesive property and there is no pectin-based or karaya material that is an integral part of a faceplate. It can be taken off the skin and reattached repeatedly. It is secured by means of a separate adhesive and/or an elastic belt. The clips for attaching the belt are usually a part of the faceplate. There is no coding distinction between flat and convex faceplates.

The following table lists codes for faceplate systems. When supplying a pouch with faceplate attached (Column I) a claim may not be made for a component product from Column II provided at the same time.

Column I	Column II
A4375	A4361, A4377
A4376	A4361, A4378
A4379	A4361, A4381, A4382

A4380	A4361, A4383
A4416	A4366
A4417	A4366
A4418	A4366
A4419	A4366
A4423	A4366
A4424	A4366
A4425	A4366
A4427	A4366

POUCHES:

A pouch is a device for collecting stomal output. A pouch for collecting bowel effluent may be either "drainable" with an opening at the bottom through which the fecal contents are emptied, or 'closed' with a sealed bottom and no outlet. A "urinary" pouch normally incorporates anti-reflux devices and a tap or spigot to empty the urine contents.

A pouch "with barrier attached" is one type of "1 piece" system in which a solid barrier is part of the pouch. There are distinct codes for 1-piece pouches with convex barriers and extended wear barriers (see "Barriers").

A pouch "without barrier attached" is a pouch with or without a thin adhesive coating that is applied either directly to the skin or to a separate barrier. It is also described as a "1 piece" system.

A pouch, which is part of a "2 piece" system, has a flange, which enables it to be coupled to a skin barrier with flange.

A pouch "with faceplate attached" or "for use on a faceplate" is generally rubber or heavy plastic. It is drainable, cleanable, and reusable for periods of weeks to months, depending on the product.

A "high output" pouch (A4412, A4413, A4435) has a capacity of greater than or equal to 0.75 liters, is drainable with a large bore solid spout with cap or plug, and is either part of a 2 piece system (A4412, A4413) or a single-piece system (A4435).

Codes for pouches with filters (e.g., A4416) describe pouches that have an opening which allows venting of trapped gas. They typically include materials such as charcoal to deodorize the vented gas. Code A4368 describes

replacement filter material.

Code A4366 describes a separate ostomy vent that can be added by the beneficiary to a pouch to allow the release of gas. This code must not be used for pouches in which a vent with a filter is incorporated in the pouch by the manufacturer. Those products are described by the codes for ostomy pouches with a filter (A4416, A4417, A4418, A4419, A4423, A4424, A4425, A4427).

Absorbent material (A4422) that is added to the ostomy pouch may come as sheets, pads or crystals.

An ostomy pouch with faucet-type tap with valve (e.g., A4429) has a valve for draining urine.

A locking flange (e.g., A4420) is a lever type flange locking mechanism. It differs from simple push-on pouch securing mechanisms. The mechanism may be incorporated either in the pouch flange or skin barrier flange (2 piece system).

PASTES:

A paste is used as a protective layer and sealant beneath ostomy appliances, and is applied directly on the skin. It may be primarily pectin based (A4406), or non-pectin based, e.g., karaya (A4405).

MISCELLANEOUS:

Code A4400 (Ostomy irrigation set) is not valid for claim submission. If an irrigation kit is supplied, the individual components should be billed using individual codes, A4397, A4398, and A4399.

Ostomy clamps (A4363) are used with drainable pouches and are not used with urinary pouches. Ostomy clamps are only payable when ordered as a replacement. Claims for ostomy clamps billed with ostomy pouches will be denied as not separately payable with ostomy pouches.

When codes A4450, A4452, and A5120 are used with ostomy supplies, they must be billed with the AU modifier. For this policy, codes A4450, A4452, and A5120 are the only codes for which the AU modifier may be used.

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

Coding Information

CPT/HCPCS Codes

N/A

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information.

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
K94.00	Colostomy complication, unspecified
K94.03	Colostomy malfunction
K94.10	Enterostomy complication, unspecified
K94.13	Enterostomy malfunction
Z43.2	Encounter for attention to ileostomy
Z43.3	Encounter for attention to colostomy
Z43.6	Encounter for attention to other artificial openings of urinary tract
Z93.2	Ileostomy status
Z93.3	Colostomy status
Z93.6	Other artificial openings of urinary tract status

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

For all HCPCS codes except A4331, A4364, A4402, A4450, A4452, A4455, A4456, A5102, A5120. All ICD-10 codes that are not specified in the previous section.

Group 1 Codes:

N/A

Additional ICD-10 Information

N/A

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

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2020	R6	<p>Revision Effective Date: 01/01/2020 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Continued medical need language</p> <p><i>06/04/2020: 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</i></p>
01/01/2020	R5	<p>Revision Effective Date: 01/01/2020 REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217): Added: Section and related information based on Final Rule 1713 CODING GUIDELINES: Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity" ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity"</p> <p><i>02/20/2020: 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</i></p>
01/01/2017	R4	<p><i>02/07/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This is an article and not a local coverage determination.</i></p>
01/01/2017	R3	<p>Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Billing Directions RELATED LOCAL COVERAGE DOCUMENTS:</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Added: Standard Documentation Language article
07/01/2016	R2	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.
10/01/2015	R1	Revision Effective Date: 08/01/2015 NON-MEDICAL NECESSITY AND PAYMENT RULES: Removed: ICD-9 references Revised: Language for HCPCS codes A4450, A4452, A5120 when submitted without correct modifier

Associated Documents

Related Local Coverage Document(s)

Article(s)

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

LCD(s)

L33828 - Ostomy Supplies

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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