Local Coverage Determination (LCD)

Negative Pressure Wound Therapy Pumps

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
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

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
				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

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
				Rhode Island Vermont
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

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
				Washington Wyoming

LCD Information

Document Information

LCD ID
L33821

LCD Title
Negative Pressure Wound Therapy Pumps

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2024

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

Issue

Issue Description
The LCD is revised to align refill requirements with CMS Final Rule CMS-1780-F. This revision allows contact with the beneficiary regarding refills to take place no sooner than 30 calendar days prior to the end of the current supply and to document an affirmative response.

Issue - Explanation of Change Between Proposed LCD and Final LCD
No proposed LCD issued.

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.

EQUIPMENT:

INITIAL COVERAGE:

Negative Pressure Wound Therapy (NPWT) is defined as the application of sub-atmospheric pressure to a wound to remove exudate and debris from wounds. NPWT is delivered through an integrated system of a suction pump, separate exudate collection chamber and dressing sets to a qualified wound. In these systems, exudate is completely removed from the wound site to the collection chamber. Refer to the CODING GUIDELINES section of the Policy Article for information about equipment and supply specifications.

Other suction pump systems (K0743, K0744, K0745, and K0746) may also be used to remove exudate from a wound. Refer to the Suction Pumps Local Coverage Determination for information about coverage of these items.

A Negative Pressure Wound Therapy pump (E2402) and supplies (A6550, A7000) are covered when either criterion A or B is met:

A. Ulcers and Wounds in the Home Setting:

The beneficiary has a chronic Stage 3 or 4 pressure ulcer (see Appendices Section), neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, must have been tried or considered and ruled out prior to application of NPWT.

1. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:

    a. Documentation in the beneficiary's medical record of evaluation, care, and wound measurements by a licensed medical professional, and
    b. Application of dressings to maintain a moist wound environment, and
    c. Debridement of necrotic tissue if present, and
    d. Evaluation of and provision for adequate nutritional status

2. For Stage 3 or 4 pressure ulcers:

a. The beneficiary has been appropriately turned and positioned, and
b. The beneficiary has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see LCD on support surfaces), and
c. The beneficiary's moisture and incontinence have been appropriately managed

3. For neuropathic (for example, diabetic) ulcers:

a. The beneficiary has been on a comprehensive diabetic management program, and
b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities

4. For venous insufficiency ulcers:

a. Compression bandages and/or garments have been consistently applied, and
b. Leg elevation and ambulation have been encouraged

B. Ulcers and Wounds Encountered in an Inpatient Setting:

1. An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating practitioner, the best available treatment option.

2. The beneficiary has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the beneficiary that will not allow for healing times achievable with other topical wound treatments).

In either situation B-1 or B-2, NPWT will be covered when treatment is ordered to continue beyond discharge to the home setting.

If criterion A or B above is not met, the NPWT pump and supplies will be denied as not reasonable and necessary.

NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds on a beneficiary. Therefore, more than one E2402 billed per beneficiary for the same time period will be denied as not reasonable and necessary.

A licensed health care professional, for the purposes of this policy, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The treating practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.

OTHER EXCLUSIONS FROM COVERAGE:

A NPWT pump and supplies will be denied at any time as not reasonable and necessary if one or more of the following are present:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure;
- Cancer present in the wound;
- The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

NPWT systems, pumps and their associated supplies, that have not been specifically designated as being qualified to use HCPCS codes E2402 via written instructions from the Pricing, Data Analysis and Coding (PDAC) Contractor will be denied as not reasonable and necessary.

CONTINUED COVERAGE:

C. For wounds and ulcers described under A or B above, once placed on a NPWT pump and supplies, in order for coverage to continue, a licensed medical professional must do the following:

1. On a regular basis,

    a. Directly assess the wound(s) being treated with the NPWT pump, and
    b. Supervise or directly perform the NPWT dressing changes, and

2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If criteria C-1 and C-2 are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not reasonable and necessary.

WHEN COVERAGE ENDS:

D. For wounds and ulcers described under A or B above, a NPWT pump and supplies will be denied as not reasonable and necessary with any of the following, whichever occurs earliest:

1. Criteria C1-C2 cease to occur,

2. In the judgment of the treating practitioner, adequate wound healing has occurred to the degree that NPWT may be discontinued,

3. Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound

4. 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using a NPWT pump in the treatment of the most recent wound

5. Once equipment or supplies are no longer being used for the beneficiary, whether or not by the treating practitioner's order

SUPPLIES:

Coverage is provided up to a maximum of 15 dressing kits (A6550) per wound per month.

Coverage is provided up to a maximum of 10 canister sets (A7000) per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day).

For high volume exudative wounds, a stationary pump with the largest capacity canister must be used.

When billing for quantities of canisters greater than those described in the policy as the usual maximum amounts, there must be clear and explicit information in the medical record that justifies the additional quantities.

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, and document an affirmative response, 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 expected to end, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply. 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 and document an affirmative response, prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request and an affirmative response 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 quantity at a time.

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

Coding Information

CPT/HCPCS Codes

Group 1 (1 Code)

Group 1 Paragraph

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

HCPCS MODIFIER:

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

GA - Waiver of liability statement issued as required by payer policy, individual case

GZ - Item or service expected to be denied as not reasonable and necessary

KX - Requirements specified in the medical policy have been met

HCPCS CODES:

EQUIPMENT

Group 1 Codes

Code	Description
E2402	NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE

Group 2 (2 Codes)

Group 2 Paragraph

SUPPLIES

Group 2 Codes

Code	Description
A6550	WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES
A7000	CANISTER, DISPOSABLE, USED WITH SUCTION PUMP, EACH

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

The staging of pressure ulcers used in this policy is as follows (National Pressure Injury Advisory Panel, 2019 Revision):

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin
Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis
Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARSI), or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Injury: Full-thickness skin loss
Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Stage 4 Pressure Injury: Full-thickness skin and tissue loss
Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining

and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss
Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

Deep Tissue Pressure Injury: Persistent non-blanchable deep red, maroon or purple discoloration
Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

N/A

Bibliography

NA

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2024	R8	**Revision Effective Date: 01/01/2024** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: “and document an affirmative response” to language that pertains to contact with the beneficiary or caregiver/designee for DMEPOS products supplied as refills Revised: “approaching exhaustion” to “expected to end” in regard to existing supplies Revised: “Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date.” to “Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the	• Provider Education/Guidance • Other (CMS Final Rule CMS-1780-F)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		current supply." Revised: "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." to "For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply." *12/14/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates to refill requirement information per CMS Final Rule CMS-1780-F.*	

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
05/01/2021	R7	**Revision Effective Date: 05/01/2021** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Revised: Roman to Arabic numerals in staging scheme Revised: “an” to “a” before NPWT APPENDICES: Revised: Updated National Pressure Ulcer Advisory Panel to National Pressure Injury Advisory Panel and 2019 guidelines (unchanged from 2016 guidelines) *03/18/2021: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due grammatical or non-substantive changes.*	• Provider Education/Guidance • Typographical Error

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2020	R6	**Revision Effective Date: 01/01/2020** 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” *As required by CR 10901, the ICD-10 information has been moved to all Policy Articles. There is no change in coverage.*	• Other

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2020	R5	**Revision Effective Date: 01/01/2020** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Revised: Format of HCPCS code references, from code 'spans' to individually-listed HCPCS Revised: "treating physician" to "treating practitioner" GENERAL: Revised: Order information as a result of Final Rule 1713 REFILL REQUIREMENTS: Revised: "ordering physicians" to "treating practitioners" DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "treating practitioner's" GENERAL DOCUMENTATION REQUIREMENTS: Revised: "Prescriptions (orders)" to "SWO"	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		02/13/2020: 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, HCPCS code changes, and non-substantive corrections (listing individual HCPCS codes instead of a HCPCS code-span).	
05/25/2017	R4	**Revision Effective Date: 05/25/2017** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: General instructions regarding WOPD	• Provider Education/Guidance
01/01/2017	R3	**Revision Effective Date: 01/01/2017** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements Revised: Supply Requirements Revised: Refill Requirements 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 Removed: Reference to Supplier	

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		Manual under Miscellaneous Revised: Pressure ulcer staging criteria per NPUAP 2016 Staging Consensus Conference Removed: PIM reference under Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	
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.	• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	Revision Effective Date: 10/01/2015 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Added: Standard Documentation Language for Dispensing Orders Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Added: Instructions for Equipment Retained from a Prior Payer Added: Repair/Replacement section Removed: Diagnosis code type reference	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A52511 - Negative Pressure Wound Therapy Pumps - Policy Article

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

Related National Coverage Documents

NCDs

N/A

Public Versions

Updated On	Effective Dates	Status	
12/07/2023	01/01/2024 - N/A	Currently in Effect	You are here

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

Keywords

N/A