

Local Coverage Determination (LCD): Negative Pressure Wound Therapy Pumps (L33821)

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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

L33821

Original ICD-9 LCD ID

[L11500](#)

[L5008](#)

[L27025](#)

[L11489](#)

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 01/01/2020

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

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.

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 III or IV 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 III or IV 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:

An 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 an 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, an 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 an 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 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 quantity at a time.

Summary of Evidence

NA

**Analysis of Evidence
(Rationale for Determination)**

NA

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 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 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

ICD-10 Codes that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

General Information

Associated Information**DOCUMENTATION REQUIREMENTS**

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

GENERAL DOCUMENTATION REQUIREMENTS

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

- 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 Ulcer Advisory Panel, 2016 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	REASON(S) FOR CHANGE
01/01/2020	R5	<p>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"</p> <p><i>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).</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance
05/25/2017	R4	<p>Revision Effective Date: 05/25/2017 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: General instructions regarding WOPD</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
01/01/2017	R3	<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 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</p>	<ul style="list-style-type: none"> • Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>Requirements</p> <p>Removed: Reference to Supplier Manual under Miscellaneous</p> <p>Revised: Pressure ulcer staging criteria per NPUAP 2016 Staging Consensus Conference</p> <p>Removed: PIM reference under Appendices</p> <p>RELATED LOCAL COVERAGE DOCUMENTS:</p> <p>Added: LCD-related Standard Documentation Requirements article</p>	
07/01/2016	R2	<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
10/01/2015	R1	<p>Revision Effective Date: 10/01/2015</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>Added: Standard Documentation Language for Dispensing Orders</p> <p>Revised: Standard Documentation Language to add who can enter date of delivery date on the POD</p> <p>Added: Instructions for Equipment Retained from a Prior Payer</p> <p>Added: Repair/Replacement section</p> <p>Removed: Diagnosis code type reference</p>	<ul style="list-style-type: none"> Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A52511 - Negative Pressure Wound Therapy Pumps - Policy Article

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

Related National Coverage Documents

N/A

Public Version(s)

Updated on 02/07/2020 with effective dates 01/01/2020 - N/A

Updated on 05/18/2017 with effective dates 05/25/2017 - 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: Negative Pressure Wound Therapy Pumps - Policy Article (A52511)

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CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
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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

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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

Article ID

A52511

Original Effective Date

10/01/2015

Original ICD-9 Article ID

[A35347](#)

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[A47111](#)

[A35425](#)

Revision Effective Date

01/01/2020

Revision Ending Date

N/A

Article Title

Negative Pressure Wound Therapy Pumps - Policy Article

Retirement Date

N/A

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

Negative pressure wound therapy equipment is 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 (LCD) must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Disposable wound suction pumps and related supplies (A9272) will be denied as statutorily noncovered because they do not meet the DME benefit.

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.

Information describing the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the beneficiary's medical record and be available for review upon request. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).

Information describing the wound evaluation and treatment, recorded in the beneficiary's medical record, must indicate regular evaluation and treatment of the beneficiary's wounds, as detailed in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD.

Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly. The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the beneficiary's medical record, in order to determine whether the equipment and supplies continue to qualify for Medicare coverage. (The supplier need not view the medical records in order to bill for continued use of NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the

supplier. However, the beneficiary's medical records may be requested in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement.)

When billing for NPWT, a diagnosis code (specific to the 5th digit or narrative diagnosis), describing the wound being treated by NPWT, must be included on each claim for the equipment and related supplies.

The medical record must include a statement from the treating practitioner describing the initial condition of the wound (including measurements) and the efforts to address all aspects of wound care (listed in A1 through A4 in the related LCD). For each subsequent month, the medical record must include updated wound measurements and what changes are being applied to effect wound healing.

Month-to-month comparisons of wound size must compare like measurements i.e. depth compared to depth or surface area compared to surface area.

If the initiation of NPWT occurs during an inpatient stay, in order to accurately account for the duration of treatment, the initial inpatient date of service must be documented. This date must be available upon request.

When NPWT therapy exceeds 4 months on the most recent wound and reimbursement ends, individual consideration for one additional month at a time may be sought using the appeals process. Information from the treating practitioner's medical record, contemporaneous with each requested one-month treatment time period extension, must be submitted with each appeal explaining the special circumstances necessitating the extended month of therapy. Note, the LCD provides coverage for the use of NPWT limited to initiating healing of the problem wounds described in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD rather than continuation of therapy to complete healing since there is no published medical literature demonstrating evidence of a clinical benefit for the use of NPWT to complete wound healing. Therefore, general, vague or nonspecific statements in the medical record such as "doing well, want to continue until healed" provide insufficient information to justify the need for extension of treatment. The medical record must provide specific and detailed information to explain the continuing problems with the wound, what additional measures are being undertaken to address those problems and promote healing and why a switch to alternative treatments alone is not possible.

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

WRITTEN ORDER PRIOR TO DELIVERY (WOPD)

Effective for claims with dates of service on or after 05/25/2017, a WOPD is no longer required.

MODIFIERS

KX, GA, and GZ Modifiers:

Suppliers must add a KX modifier to a code only if all of the criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD have been met.

The KX modifier must not be used with an NPWT pump and supplies for wounds if:

1. The pump has been used to treat a single wound and the claim is for the fifth or subsequent month's rental, or
2. The pump has been used to treat more than one wound and the claim is for the fifth or subsequent month's rental after therapy has begun on the most recently treated wound. In this situation, the KX modifier may be billed for more than four total months of rental.

In all of the situations above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to a claim line for the NPWT pump and supplies. When there is an expectation of a reasonable and necessary denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

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

CODING GUIDELINES

NPWT is provided with an integrated system of components. This system contains a pump (E2402), dressing sets (A6550) and a separate collection canister (A7000). Wound suction systems that do not contain all of the required components are not classified as NPWT. See below for component specifications.

EQUIPMENT:

Code E2402 describes a stationary or portable Negative Pressure Wound Therapy (NPWT) electrical pump which provides controlled sub-atmospheric pressure that is designed for use with NPWT dressings (A6550) and canisters (A7000) to promote wound healing. The NPWT pump must be capable of being selectively switched between continuous and intermittent modes of operation and is controllable to adjust the degree of sub-atmospheric pressure conveyed to the wound in a range of 40-80 mm Hg sub-atmospheric pressure. The system must contain sensors and alarms to monitor pressure variations and exudate volume in the collection canister.

Disposable wound suction system pumps and related supplies must be coded A9272 (WOUND SUCTION, DISPOSABLE, INCLUDES DRESSING, ALL ACCESSORIES AND COMPONENTS, ANY TYPE, EACH).

SUPPLIES:

Code A6550 describes an allowance for a dressing set which is used in conjunction with a stationary or portable NPWT pump (E2402). A single code A6550 is used for each single, complete dressing change, and contains all necessary components, including but not limited to any separate, non-adherent porous dressing(s), drainage tubing, and an occlusive dressing(s) which creates a seal around the wound site for maintaining sub-atmospheric pressure at the wound.

HCPCS code A7000 describes a canister set which is used in conjunction with a stationary or portable NPWT pump and contains all necessary components, including but not limited to a container, to collect wound exudate. Canisters may be various sizes to accommodate stationary or portable NPWT pumps.

Supplies used with disposable wound suction systems that are separately billed must be coded as A9900 (MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE).

The only products which may be billed using codes E2402 are those for which a written Coding Verification Review has been made by the Pricing, Data Analysis and Coding (PDAC) Contractor and subsequently published on the appropriate Product Classification List.

Suppliers should contact the PDAC for guidance on the correct coding of these items.

Coding Information

CPT/HCPCS Codes

N/A

ICD-10 Codes that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

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</p> <p>REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217):</p> <p>Added: Section and related information based on Final Rule 1713</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</p> <p>Revised: "physician" to "practitioner"</p> <p>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:</p> <p>Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity"</p> <p>ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:</p> <p>Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity"</p> <p><i>02/13/2020: 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>
05/25/2017	R5	<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>
05/25/2017	R4	<p>Revision History Effective Date: 05/25/2017</p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:</p> <p>Removed: WOPD requirement</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</p> <p>Removed: WOPD requirement</p>
01/01/2017	R3	<p>Revision History Effective Date: 01/01/2017</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</p> <p>Added: Billing Information, Written Order Prior to Delivery and Modifiers requirements</p> <p>RELATED LOCAL COVERAGE DOCUMENTS:</p> <p>Added: LCD-related Standard Documentation Requirements Language Article</p>
07/01/2016	R2	<p>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.</p>
10/01/2015	R1	<p>Revision Effective Date: 10/01/2015</p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:</p> <p>Added: HCPCS Code A9272 (code effective 01/01/2012) to statement regarding denial of disposable wound suction pumps and related supplies</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		CODING GUIDELINES: Added: Instructions for billing disposable wound suction system Revised: Instructions for billing supplies used with disposable wound suction systems

Associated Documents

Related Local Coverage Document(s)

Article(s)

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

LCD(s)

L33821 - Negative Pressure Wound Therapy Pumps

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 02/07/2020 with effective dates 01/01/2020 - N/A

Updated on 01/31/2019 with effective dates 05/25/2017 - N/A

Updated on 05/18/2017 with effective dates 05/25/2017 - N/A

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Keywords

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