

## LCD for Negative Pressure Wound Therapy Pumps (L11500)

### Contractor Information

**Contractor Name**

[NHIC, Corp.](#)

**Contractor Number**

16003

**Contractor Type**

DME MAC

### LCD Information

**LCD ID Number**

L11500

**LCD Title**

Negative Pressure Wound Therapy Pumps

**Contractor's Determination Number**

NPWT

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**CMS National Coverage Policy**

None

**Primary Geographic Jurisdiction**

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Massachusetts  
Maryland  
Maine  
New Hampshire  
New Jersey  
New York - Entire State  
Pennsylvania  
Rhode Island  
Vermont

## LCD Information

### Oversight Region

Region I

### DME Region LCD Covers

Jurisdiction A

### Original Determination Effective Date

For services performed on or after 10/01/2000

### Original Determination Ending Date

### Revision Effective Date

For services performed on or after 10/01/2009

### Revision Ending Date

### Indications and Limitations of Coverage 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. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

EQUIPMENT:

INITIAL COVERAGE:

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

A) Ulcers and Wounds in the Home Setting:

The patient 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, should 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 patient's medical record of evaluation, care, and wound

## LCD Information

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

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

- a. The patient 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 physician, the best available treatment option.
2. The patient 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 patient 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 continuation is ordered 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 medically necessary.

NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds on a patient. Therefore, more than one E2402 billed per patient for the same time period will be denied as not medically 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 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 medically necessary if one or more of the following are present:

## LCD Information

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound;
- The presence of a fistula to an organ or body cavity within the vicinity of the wound.

NPWT pumps and their supplies, that have not been specifically designated as being qualified to use HCPCS code E2402 via written instructions from the Pricing, Data Analysis and Coding (PDAC) Contractor will be denied as not medically 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 medically 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 medically necessary with any of the following, whichever occurs earliest:

1. Criteria C1-C2 cease to occur,
2. In the judgment of the treating physician, 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 patient, whether or not by the physician's order.

### SUPPLIES:

Coverage is provided up to a maximum of 15 dressing kits (A6550) per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.

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.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers may dispense a maximum of one month's supply of dressing kits or canisters at any one time.

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The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has "authorized" this in advance. As referenced in the Program Integrity Manual (Internet-Only Manual, CMS Pub. 100-8, Chapter 4.26.1) "Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product."

### Coverage Topic

Durable Medical Equipment

### Coding Information

#### CPT/HCPCS Codes

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 on file

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

E2402 NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE

SUPPLIES

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-9 Codes that Support Medical Necessity

Not specified.

#### Diagnoses that Support Medical Necessity

Not specified.

#### ICD-9 Codes that DO NOT Support Medical Necessity

Not specified

#### ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

#### Diagnoses that DO NOT Support Medical Necessity

Not specified.

## General 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" (42 U.S.C. section 1395l (e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items delivered before a signed written order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

Documentation of the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the patient'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.).

Documentation of wound evaluation and treatment, recorded in the patient's medical record, must indicate regular evaluation and treatment of the patient's wounds, as detailed in the Indications and Limitations of Coverage Section. 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 patient'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 patient'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, an ICD-9-CM 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 physician describing the initial condition of the wound (including measurements) and the efforts to address all aspects of wound care (listed in A1 through A4). For each subsequent month, the medical record must include updated wound measurements and what changes are being applied to effect wound healing.

When NPWT therapy exceeds 4 months on the most recent wound and reimbursement ends, individual consideration for additional months may be sought using the appeals process. Documentation should be submitted with the appeal explaining the special circumstances necessitating the extended therapy time.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, there must be clear documentation in the medical record corroborating the medical necessity for the additional quantities.

KX, GA and GZ MODIFIERS:

## General Information

Suppliers must add a KX modifier to a code only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy 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 5th or subsequent month's rental, or
2. The pump has been used to treat more than one wound and the claim is for the 5th 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 4 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 medical necessity 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.

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

## Appendices

The staging of pressure ulcers used in this policy is as follows:

**Suspected Deep Tissue Injury:** Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

**Stage I -** Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

**Stage II -** Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

**Stage III -** Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

**Stage IV -** Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

**Unstageable:** Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

## Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

## Sources of Information and Basis for Decision

National Pressure Ulcer Advisory Panel (NPUAP) Revised Staging Definitions for Pressure Ulcers accessed at [npuap](http://npuap.org) on August 28, 2008.

## General Information

### Advisory Committee Meeting Notes

### Start Date of Comment Period

### End Date of Comment Period

### Start Date of Notice Period

10/01/2000

### Revision History Number

NPWT007

### Revision History Explanation

#### Revision Effective Date: 10/01/2009

##### INDICATIONS AND LIMITATIONS OF COVERAGE:

Added: Program Integrity Manual instructions on refills of supplies.

Changed: SADMERC to PDAC.

##### HCPCS CODES AND MODIFIERS:

Added: GA and GZ modifiers.

Revised: KX modifier.

##### DOCUMENTATION REQUIREMENTS:

Added: Instructions for the use of GA and GZ modifiers.

##### APPENDICES:

Revised: Pressure ulcer staging based on NPUAP guidelines.

##### SOURCES OF INFORMATION AND BASIS FOR DECISION:

Added: Reference to NPUAP guidelines for pressure ulcer staging.

**03/01/2008** - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L11500 from DME PSC TriCenturion (77011) LCD L11500.

#### Revision Effective Date: 07/01/2007

##### INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY

Moved: Documentation requirements for extra supplies to the Documentation Requirements section of the LCD.

Removed: DMERC references.

##### DOCUMENTATION REQUIREMENTS:

Revised: Documentation requirements for extra supplies.

Removed: DMERC references.

**06/01/2007** - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

## General Information

### **Revision Effective Date: 07/01/2006**

INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY

Removed: Individual consideration language from "When Coverage Ends" section.

DOCUMENTATION SECTION:

Corrected: Reference to "Indications" section.

**03/01/2006** - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

### **Revision Effective Date: 01/01/2006**

INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY:

Removed: HCPCS codes A6550 and A6551 as requiring SADMERC verification.

Deleted: A6551 and inserted canister code A7000 as having a maximum of 10 canisters allowable per month.

HCPCS CODES AND MODIFIERS:

Added: A7000

Deleted: A6551

Revised: A6550

### **Revised Effective Date: 10/01/2005**

LMRP converted to LCD and Policy Article.

INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY:

Revised: Criteria D3 & D4.

DOCUMENTATION REQUIREMENTS:

Revised: Instructions for use of KX modifier.

Removed: Requirement for additional documentation being submitted in the 5th month.

### **Revised Effective Date: 04/01/2004**

HCPCS CODES & MODIFIERS:

Added: New HCPCS codes E2402, A6550, A6551.

Deleted: K0538, K0539, K0540.

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added: References to new codes and removed deleted codes.

CODING GUIDELINES:

Added: References to new codes and removed deleted codes.

### **Revised Effective Date: 04/01/2003**

HCPCS CODES AND MODIFIER:

Added: EY modifier.

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added: Standard language concerning coverage of items without an order.

DOCUMENTATION REQUIREMENTS:

Added: Standard verbiage concerning use of EY modifier for items without an order.

Added: Language regarding extra quantities being ordered and the need for documentation with each claim for excess quantities as well as in the patient's medical record to corroborate medical necessity.

**The revision date listed below is the date the revision was published and not necessarily the effective date for the revision.**

07/01/2002 - Staging of pressure ulcers revised under Definition section. Section E, which is no longer applicable at this time, has been deleted from the Coverage and Payment Rules section. Replaced ZX modifier with KX modifier.

## Reason for Change

## General Information

**Last Reviewed On Date**

**Related Documents**

**Article(s)**

[A35347 - Negative Pressure Wound Therapy Pumps - Policy Article - Effective October 2009](#)

**LCD Attachments**

There are no attachments for this LCD

**Article for Negative Pressure Wound Therapy Pumps - Policy Article - Effective October 2009 (A35347)**

**Contractor Information**

**Contractor Name**

[NHIC, Corp.](#)

**Contractor Number**

16003

**Contractor Type**

DME MAC

**Article Information**

**Article ID Number**

A35347

**Article Type**

Article

**Key Article**

Yes

**Article Title**

Negative Pressure Wound Therapy Pumps - Policy Article - Effective October 2009

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**[Primary Geographic Jurisdiction](#)**

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Maine  
New Hampshire  
New Jersey  
New York - Entire State  
Pennsylvania  
Rhode Island  
Vermont

## Article Information

### DME Region Article Covers

Jurisdiction A

### Original Article Effective Date

10/01/2005

### Article Revision Effective Date

10/01/2009

### Article Text

#### **NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

For an item addressed in this policy to be covered by Medicare, a written signed and dated order must be received by the supplier prior to delivery of the item. If the supplier delivers the item prior to receipt of a written order, it will be denied as noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

#### **CODING GUIDELINES**

##### **EQUIPMENT:**

Code E2402 describes a stationary or portable Negative Pressure Wound Therapy (NPWT) electrical pump which provides controlled subatmospheric pressure that is designed for use with NPWT dressings, (A6550) to promote wound healing. Such an NPWT pump is capable of being selectively switched between continuous and intermittent modes of operation and is controllable to adjust the degree of subatmospheric pressure conveyed to the wound in a range of at least 40-80 mm Hg subatmospheric pressure.

##### **SUPPLIES:**

Code A6550 describes a dressing set which is used in conjunction with a stationary or portable NPWT pump (E2402), and contains all necessary components, including but not limited to non-adherent porous dressing, drainage tubing, and an occlusive dressing which creates a seal around the wound site for maintaining subatmospheric 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.

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.

#### **Coverage Topic**

Durable Medical Equipment

## Coding Information

No Coding Information has been entered in this section of the article.

## Other Information

### Revision History Explanation

**Revision Effective Date: 10/01/2009**

CODING GUIDELINES:

Changed: SADMERC to PDAC.

**03/01/2008** - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A35347 from DME PSC TriCenturion (77011) Article A35347.

**06/01/2007** - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

**03/01/2006** - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

**Revision Effective Date: 01/01/2006**

CODING GUIDELINES:

Revised: Definitions for codes E2402 and A6550.

Inserted: Canister HCPCS code A7000.

Removed: Deleted canister coder A6551 where applicable.

Added: Statement about Coding Verification Review for code E2402.

**Revision Effective Date: 10/01/2005**

LMRP converted to LCD and Policy Article.

### Related Documents

**LCD(s)**

[L11500 - Negative Pressure Wound Therapy Pumps](#)