# Local Coverage Determination (LCD) for Negative Pressure Wound Therapy Pumps (L11500)

## Contractor Information

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## LCD Information

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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. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For these items to be covered by Medicare, a written order prior to delivery (WOPD) is required. Refer to the DOCUMENTATION REQUIREMENTS section of this LCD and to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for information about WOPD prescription requirements.

EQUIPMENT:

INITIAL COVERAGE:

Negative Pressure Wound Therapy (NPWT) is defined as the application of subatmospheric 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 – 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 physician, 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 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 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 beneficiary, 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.

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.

For Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS) items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A6550 and A7000) 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/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. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

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 ordering physicians 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.

**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.

**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.

**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:
E2402 NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE

Group 2 Paragraph: SUPPLIES
Group 2 Codes:
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

ICD-9 Codes that DO NOT Support Medical Necessity
Not specified

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 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.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. 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 dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

WRITTEN ORDERS PRIOR TO DELIVERY (PIM 5.2.3.1)

A detailed written order prior to delivery (WOPD) is required for Negative Pressure Wound Therapy devices and supplies. The supplier must have received a WOPD that has been both signed and dated by the treating physician and meets the requirements for a DWO before dispensing the item.

DETAILED WRITTEN ORDERS (PIM 5.2.3)
A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use, if applicable
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills or length of need

For the “Date of the order” described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state “PRN” or “as needed” utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

**MEDICAL RECORD INFORMATION**

**GENERAL (PIM 5.7 - 5.9)**

The **Coverage Indications, Limitations and/or Medical Necessity** section of this LCD contains numerous reasonable and necessary (R&N) requirements. The **Non-Medical Necessity Coverage and Payment Rules** section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.
Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial DOS to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating physician for refills
- A recent change in prescription
- A properly completed CMN or DIF with an appropriate length of need specified
- Timely documentation in the beneficiary's medical record showing usage of the item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

1. Timely documentation in the beneficiary’s medical record showing usage of the item, related option/accessories and supplies
2. Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)
3. Supplier records documenting beneficiary confirmation of continued use of a rental item
Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

REFILL DOCUMENTATION (PIM 5.2.5-6)

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a prescription renewal

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- For consumable supplies i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.) - The Supplier should assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) - The supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.
Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. For items addressed in this policy there are two methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service

**Method 1—Direct Delivery to the Beneficiary by the Supplier**

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery slip. The POD record must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the item is delivered directly by the supplier, the date the beneficiary received the DMEPOS item must be the date of service on the claim.

**Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary**

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD record must contain the information specified above.
POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

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. 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, 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. 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 physician’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, this policy 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 this 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 policy as the usual maximum amounts, there must be clear and explicit information in the medical record that justifies the additional quantities.

**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 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 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.

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

**Appendices**

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-8

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 Coverage Indications, Limitations and/or Medical Necessity

Sources of Information and Basis for Decision

### Revision History Information

**Please note:** The Revision History information included in this LCD prior to 1/24/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 1/24/2013 will display as a row in the Revision History section of the LCD and numbering will begin with "R2".

<table>
<thead>
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<td>Revision Effective Date: 07/01/2013 (April 2014 Publication) COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Information that referenced ACA 6407 requirements - The ACA 6407 requirements were incorrectly included in this policy POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: ACA 6407 information - The ACA 6407 requirements were incorrectly included in this policy</td>
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<td>R2</td>
<td>Revision Effective Date: 10/01/2011 (April 2013 Publication) COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Order requirement language to specify a “detailed written order” Changed: Word “Patient” to “Beneficiary”</td>
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| 10/01/2011            | R1                      | **Revision Effective Date: 10/01/2011**  
**INDICATIONS AND LIMITATIONS OF COVERAGE AND MEDICAL NECESSITY:**  
Added: Definition for NPWT systems and wound suction systems  
Revised: A6550 quantities statement to be consistent with the HCPCS narrative all-inclusive definition  
Revised: Untreated osteomyelitis exclusion  
Added: Reference statement for wound suction pumps and associated dressings pointing to Suction Pump LCD.  
Revised: Supplies refill monitoring and dispensing instructions. (Effective 08/02/2011)  
**DOCUMENTATION REQUIREMENTS:**  
Revised: Preamble  
Added: Statement about comparison of wound measurements  
Added: Statement about initial inpatient start date.  
Added: Statement about documentation for treatment past the initial 4-months  
Revised: Length of need for the prescription  
Revised: Appeals information for extended months of treatment  
Added: Refill Documentation guidelines. (Effective 08/02/2011)  
| Maintenance (annual review with new changes, formatting, etc.) |
| 10/01/2011            |                         | **Revision Effective Date: 01/01/2011**  
**INDICATIONS AND LIMITATIONS OF COVERAGE AND MEDICAL NECESSITY:**  
Revised: Preamble  
Revised: “medically necessary” replaced with “reasonable and necessary”  
**HCPCS CODES AND MODIFIERS**  
Revised: GA narrative  
**DOCUMENTATION REQUIREMENTS:**  
Revised: “medically necessary” replaced with “reasonable and necessary”  
<p>| | 10/01/2009 | <strong>Revision Effective Date: 10/01/2009</strong> | |</p>
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<td>Indicates and limitations of coverage:</td>
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<td>Added: Program Integrity Manual instructions on refills of supplies.</td>
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<td>Changed: SADMERC to PDAC.</td>
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<td>Hcpcs codes and modifiers:</td>
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<td>Added: GA and GZ modifiers.</td>
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<td>Added: Instructions for the use of GA and GZ modifiers.</td>
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<td>Revised: Pressure ulcer staging based on NPUAP guidelines.</td>
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<td>Sources of information and basis for decision:</td>
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<td>Added: Reference to NPUAP guidelines for pressure ulcer staging.</td>
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<td>Moved: Documentation requirements for extra supplies to the documentation requirements section of the LCD.</td>
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<td>Removed: Individual consideration language from “When Coverage Ends” section.</td>
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<td>Documentation section:</td>
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<td>Corrected: Reference to “Indications”</td>
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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:
Revision History | Revision History Number | Revision History Explanation | Reason(s) for Change
--- | --- | --- | ---
|  |  | 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.

**Associated Documents**

**Attachments**
N/A

**Related Local Coverage Documents**

**Article(s)**
A35347 - Negative Pressure Wound Therapy Pumps - Policy Article - Effective July 2013

**Related National Coverage Documents**

**All Versions**
Updated on 03/28/2014 with effective dates 07/01/2013 - N/A
Updated on 03/07/2014 with effective dates 07/01/2013 - N/A
Updated on 04/05/2013 with effective dates 10/01/2011 - 06/30/2013
Updated on 03/05/2012 with effective dates 10/01/2011 - N/A
Updated on 08/19/2011 with effective dates 10/01/2011 - N/A
Updated on 02/27/2011 with effective dates 01/01/2011 - 09/30/2011
Updated on 02/25/2011 with effective dates 01/01/2011 - N/A
Updated on 07/23/2009 with effective dates 10/01/2009 - 12/31/2010
Updated on 07/23/2009 with effective dates 10/01/2009 - N/A
Updated on 07/23/2009 with effective dates 10/01/2009 - N/A
Updated on 02/19/2008 with effective dates 07/01/2007 - 09/30/2009

**Keywords**
N/A
Local Coverage Article for Negative Pressure Wound Therapy Pumps - Policy Article - Effective July 2013 (A35347)

Contractor Information

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<tr>
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<td>16003</td>
<td>DME MAC</td>
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Article Information

General Information

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<td>A35347</td>
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Article Title

Negative Pressure Wound Therapy Pumps - Policy Article - Effective July 2013

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Original Effective Date

10/01/2005

Revision Effective Date

07/01/2013

Revision Ending Date

N/A

Retirement Date

N/A

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. In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable
and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

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.

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

**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 subatmospheric 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 subatmospheric pressure conveyed to the wound in a range of 40-80 mm Hg subatmospheric pressure. The system must contain sensors and alarms to monitor pressure variations and exudate volume in the collection canister.

Disposable wound suction system pumps must be coded A9270 (Noncovered item or service).

**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 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.

Supplies used with disposable wound suction systems must be coded as A9270 (Noncovered item or service).
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**

**Bill Type Codes:**
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the article services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

**CPT/HCPCS Codes**
N/A

**Covered ICD-9 Codes**
N/A

**Non-Covered ICD-9 Codes**
N/A

**Revision History Information**

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<td>R3</td>
<td><strong>Revision Effective Date: 07/01/2013 (April 2014 Publication)</strong> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: Information that referenced ACA 6407 requirements - The ACA 6407 requirements were incorrectly included in this policy.</td>
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<td>07/01/2013</td>
<td>R2</td>
<td><strong>Revision Effective Date: 07/01/2013</strong> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: ACA 6407 requirements</td>
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<tr>
<td>10/01/2011</td>
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<td>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.</td>
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### Associated Documents

**Related Local Coverage Document(s)**

- LCD(s)
- L11500 - Negative Pressure Wound Therapy Pumps

**Related National Coverage Documents**

**Statutory Requirements URL(s)**