Negative Pressure Wound Therapy Pumps

Adopted from the National Government Services website.

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan 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. Please refer to individual product lines certificates of coverage for possible exclusions of benefit.

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

NPWT require precertification. Reimbursement and or coverage of some codes may be subject to specific contract information

Disposable wound suction pumps and related supplies will be denied as noncovered as they do not meet the definition of DME.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>Jurisdiction B</td>
</tr>
<tr>
<td>Review/Revisions Effective Date</td>
<td>For services performed on or after: 10/31/13 Review/Revised on: 04/10/17, 05/01/16, 9/12/14</td>
</tr>
<tr>
<td>The Health Plan</td>
<td>Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents.</td>
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DESCRIPTION

Negative pressure wound therapy (NPWT) completely removes the exudates from the wound site into a collection chamber using subatmospheric pressure. It contains a pump (E2402), dressing sets (A6550), and a separate collection canister (A7000). These are different from suction pumps (K0743 - K0746) where the exudates collect in the dressing. Please refer to the Suction Pump policy for information regarding codes K0743 - K0746.
COVERAGE GUIDELINES

Ulcers and Wounds in the Home Setting:

There is evidence of a chronic Stage III or IV pressure ulcer (see Medicare definitions and description 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. Wound systems are only covered, based on the type of wound, when other treatments indicated below have been tried and failed.

1. For all ulcers or wounds, documentation of a wound therapy program which includes all of the following general measures, as being either be addressed, applied, or considered and ruled out prior to the request of NPWT:
   a. Documentation in the medical record of evaluation, care, and wound measurements by a licensed medical professional, and
   b. Debridement of necrotic tissue if present, and
   c. Evaluation of and provision for adequate nutritional status.
   d. Application of appropriate dressings

2. For Stage III/IV pressure ulcers:
   a. Appropriately turning and positioning has been performed, and
   b. Group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis has been utilized (see policies on support surfaces),
   c. Moisture and incontinence have been appropriately managed.

3. For neuropathic (for example, diabetic) ulcers:
   a. There is documentation of 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.

5. Complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, preoperative 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 that will not allow for healing times achievable with other topical wound treatments).

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 must be submitted with precertification.

The provider is to educate the member on when to call a physician or 911 if a medical emergency arises.

Suppliers should have a program promoting safe use of the equipment and how to minimize safety risks and transmission of infection.

There should be policies in place by the provider demonstrating that the equipment is cleaned between uses by different beneficiaries per the manufacturers’ recommendations.
COVERAGE GUIDELINES FOR SUPPLIES

Coverage is provided up to a maximum of 15 dressing kits (A6550) per wound per month unless there is specific documentation that supports the request (i.e., 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.

Reminder to providers: Adaptic may be used in the following situations:

- To cover staples
- To protect vessels, organs, tendons, ligaments, and nerves
- To protect exposed bone
- Foam dressing has adhered to wound base

Provider is to clarify why white nonadherent foam would not be effective.

A precertification is required for requests above the allowable amounts

CONTINUED COVERAGE PAST THIRD MONTH

For continued coverage of the NPWT pump past the third month, the following information must be submitted:

1. The wound information from the second and third month listed in the documentation requirements section below, and what changes are being applied to effect wound healing.
2. If medically appropriate, one month extension will be authorized.
3. If the criteria above are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not meeting coverage guidelines.

WHEN COVERAGE ENDS

The NPWT pump and supplies will be denied for not meeting criteria with any of the following, whichever occurs earliest:

4. In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
5. 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 x width) or depth of the wound.
6. Once equipment or supplies are no longer being used by the member, whether or not by the physician’s order.
7. Four 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. See “Continued Coverage Past Fourth Month.”
CONTINUED COVERAGE PAST FOURTH MONTH

**NOTE:** The physician is to submit information from the medical record explaining reason for extension, the special circumstances with specific detailed information as to what additional interventions are being undertaken and why switching to an alternative dressing would not be appropriate.

If extension is authorized, it will be for one month at a time. New information from the physician required for each months’ extension.

**Note:** Nonspecific, vague, generalized statements and physician attestation alone is not sufficient for authorization, i.e., “Wound doing well and want to continue vac.” or “I (physician) attest that (member) requires a wound vac for continued healing.” would not be considered acceptable documentation.

NONCOVERAGE STATEMENT

NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds. Therefore, more than one E2402 billed for the same time period will be denied.

An NPWT pump and supplies is contraindicated in any of the following circumstances:

- 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 a fistula to an organ or body cavity within the vicinity of the wound.

The following are examples of wound suction devices that are not considered negative pressure devices and therefore not covered:

Disposable wound suction devices (A9270, A9272), as they do not meet the definition of DME and are statutorily noncovered by Medicare and Medicaid. Examples would be the SNaP (Spiracure) device, and the PICO (Smith and Nephew), and the Vac Via (KCI). These devices are not covered across all Lines of Business.

**Note:** Medicare is allowing for NWPT using a disposable device for wound care under Hospital Based Outpatient/Ambulatory Payment Classification or Home Health Nursing care. However, the service is not billed under DME HCPCS code but CPT codes 97607 and 97608 with status indicator T, depending.. Please refer to Medlearn Matters MM9736 for Instructions. Links noted at the end of this policy.
NEGATIVE PRESSURE WOUND THERAPY PUMPS

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>EY</td>
<td>NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE</td>
</tr>
<tr>
<td>GA</td>
<td>WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CASE</td>
</tr>
<tr>
<td>GZ</td>
<td>ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY</td>
</tr>
<tr>
<td>KX</td>
<td>REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET</td>
</tr>
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</table>

HCPCS CODES

EQUIPMENT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E2402</td>
<td>NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, STATIONARY OR PORTABLE</td>
</tr>
<tr>
<td>A9270</td>
<td>NONCOVERED ITEM OR SERVICE</td>
</tr>
</tbody>
</table>

SUPPLIES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>A6550</td>
<td>WOUND CARE SET, FOR NEGATIVE PRESSURE WOUND THERAPY ELECTRICAL PUMP, INCLUDES ALL SUPPLIES AND ACCESSORIES</td>
</tr>
<tr>
<td>A7000</td>
<td>CANISTER, DISPOSABLE, USED WITH SUCTION PUMP, EACH</td>
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</tbody>
</table>

There are no specific diagnoses or ICD-10 codes that indicate medical necessity.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes 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 with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
a. Member’s name
b. Date of order and date of initial delivery
c. Order must include any specific feature of the base code and every addition requested. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification if the item requires precertification, or with the claim, if no precertification was required
d. Order must include diagnosis code. For NWPT device, the initial order will only be valid up through the first 4 months
e. Physician signature with date. Date stamps are not appropriate

2. Proof of delivery to be kept on file by the provider of the item.

3. If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

4. Documentation of the history, previous treatment regimens (if applicable), and current wound management, including:
   a. Length of sessions of use, and
   b. Dressing types and frequency of change, and
   c. Changes in wound conditions, including precise measurements, and
   d. Quantity of exudates, presence of granulation and necrotic tissue and
   e. Concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.)

5. Documentation must indicate a regular evaluation and treatment of the wounds, including:
   a. Quantitative measurements of wound characteristics, including wound length and width (surface area), wound depth, amount of wound exudate (drainage), and indicating progress of healing must be entered at least monthly. And,
   b. Month-to-month comparisons of wound size must compare like measurements (i.e., depth compared to depth or surface area to surface area).

**Note:** The provider 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 medical record, in order to determine whether the equipment and supplies continue to qualify for coverage. The medical records may be requested in order to corroborate that wound healing is/was occurring.

Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

**COVERAGE OF NWPT WHILE MEMBER IN PART A FACILITY**

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 and submitted with precertification.
Reimbursement for NWPT provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility. If the member is discharged from a Part A level of service and the medical necessity for the NWPT is still documented, it will be reviewed for continued coverage.

EQUIPMENT RETAINED FROM A PRIOR PAYOR:
The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

DISPENSING SUPPLIES
The Health Plan is following Medicare guidelines for supplies provided on reoccurring basis.
Suppliers are not to automatically dispense supplies according to allowable limits. Suppliers are required to reorder supplies based on actual usage of each member. There must be a specific request for the supplies from the member or caregiver prior to dispensing the supplies. Supplies should not be shipped/delivered sooner than 10 days prior to end of usage. Please refer to CMS Program Integrity Manual for more information. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

The DME supplier is responsible to monitor utilization of rented and covered frequently purchase supplies for member owned equipment that they would be requesting reimbursement from The Health Plan.

Utilization above the current allowable quantities will not be reimbursed unless corroborated by medical record of the medical necessity of the quantity of supplies being used.

KX, GA, and GZ MODIFIERS
Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.
If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical 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).

ADVANCED BENEFICIARY NOTICE
The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.
PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare’s PDAC contractor for review of authorizations. The only products which may be billed using codes E2402 are those for which a written coding verification review has been made by PDAC contractor and subsequently published on the appropriate product classification list. [dmepdac.com](http://dmepdac.com/)

MEDICARE DEFINITIONS AND DESCRIPTION

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.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I</td>
<td>Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.</td>
</tr>
<tr>
<td>Stage II</td>
<td>Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.</td>
</tr>
<tr>
<td>Stage III</td>
<td>Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.</td>
</tr>
<tr>
<td>Stage IV</td>
<td>Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.</td>
</tr>
</tbody>
</table>

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.

Code **E2402** describes a stationary or portable 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. The system contains sensors and alarms to monitor pressure variations and exudates volume in the collection canister.

**Disposable wound suction system suction pumps must be coded A9270.**

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(s), drainage tubing, and an occlusive dressing(s), which creates a seal around the wound site for maintaining subatmospheric pressure at the wound (1 unit A6550 =1 complete dressing change).
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.

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INTERNET LINKS AND SOURCES

National Government Services Local Coverage Determination Policy Website. Negative Pressure Wound Therapy. LCD L27025 and Article A47111. Last accessed 04/01/16. Retrieved from http://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home­lob/ut/p/a1/04_Sj9CPykssy0XPfMnMzOvMAFGjzOJNHD1dDQ2dDbz9nV0dDRxNPZm_BzdDP0NTJEKIEU GPtbABW4Obm4BAYYusZEAffAAdwNCckP1w_Ck0jgvyACvBYUZAbGmGQ6agIAl1i1Es1/dl5/d5/L2dBiSEv Z0FBIS9nQSEh/?LOB=DME&LOC=Ohio&ngsLOC=Ohio&ngsLOB=DME&jurisdiction=Jurisdiction%20B


National Pressure Ulcer Advisory Panel (NPUAP) Revised Staging Definitions for Pressure Ulcers. Last accessed 04/01/16. Retrieved from npuap.org/