

Medical Policy



Negative Pressure Wound Therapy Pumps and Wound Suction Pumps

▼ Description

Negative pressure wound therapy (NPWT) is the controlled application of subatmospheric pressure to a wound using an electrical pump to intermittently or continuously convey subatmospheric pressure through connecting tubing to a specialized wound dressing system sealed with an occlusive dressing that is meant to contain the subatmospheric pressure at the wound site and thereby promote wound healing. Drainage from the wound is collected in a canister.

Wound suction pumps (K0743) also provide subatmospheric pressure to the wound but differ in that they do not utilize a separate collection canister. Instead, exudate is retained in the dressing materials (K0744- K0746).

Disposable wound suction pumps and related supplies are considered not reasonable and necessary because they do not meet the definition of DME (A9272)

▼ Policy

Negative pressure wound therapy and associated supplies are considered **reasonable and necessary** when a Member meets coverage criteria A or B outlined below and is ordered by the Member's treating physician.

INITIAL COVERAGE:

A) Ulcers and Wounds in the Home Setting:

The member has a chronic Stage 3 or 4 pressure ulcer, 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 member's medical record of evaluation, care, and wound measurements by a licensed medical professional, and
- b. Application of dressings to maintain a moist wound environment, and
- c. Debridement of necrotic tissue if present, and
- d. Evaluation of and provision for adequate nutritional status.

2. For Stage 3 or 4 pressure ulcers:

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

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

- a. The member 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 in 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 member 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 member 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 reasonable and necessary.

NPWT pumps (E2402) must be capable of accommodating more than one wound dressing set for multiple wounds on a member. Therefore, more than one E2402 billed per member 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 member is receiving NPWT.

OTHER EXCLUSIONS FROM COVERAGE:

- 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 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 will be denied as not reasonable and necessary.

CONTINUED COVERAGE:

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

1. On a regular basis,
 - a. Directly assess the wound(s) being treated with the NPWT pump, and
 - b. Supervise or directly perform the NPWT dressing changes, and
2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

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

WHEN COVERAGE ENDS:

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

1. Criteria C1-C2 cease to occur,
2. In the judgement 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 a NPWT pump in the treatment of the most recent wound.
5. Once equipment or supplies are no longer being used for the member, 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 90ml of exudate per day). For high volume exudative wounds, a stationary pump with the largest capacity canister must be used.

Providers 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.

WOUND SUCTION PUMP:

Wound suction is provided with an integrated system of components. This system contains a pump (K0743) and dressing sets (K0744 – K0746). It does not include a separate collection canister (A7000), a defining component of Negative Pressure Wound Therapy (NPWT). Instead, exudate is retained in the dressing materials. Therefore, wound suction systems are not classified as NPWT systems. (These codes will be added to the Suction Pump policy in the future).

Systems that do not contain all of the required components are not classified as wound suction systems.

Code K0743 describes a suction pump for wounds which provides controlled subatmospheric pressure that is designed for use with dressings, K0744 – K0746 without a canister.

Codes K0744 – K0746 describe an allowance for dressing sets that are used in conjunction with a stationary or portable suction pump (K0743) but not used with a canister. Each of these codes K0744- K0746 is used for a single, complete dressing change, 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. These dressing sets are selected based upon wound size using the smallest size necessary to cover the wound. For multiple wounds located close together, a single large dressing must be used rather than multiple smaller dressing sets if it is possible to fit the wounds under a single larger dressing set.

Disposable wound suction system pumps must be coded A9270 (non-covered item or service).

Supplies, including dressings, used with disposable wound suction systems must be coded as A9270 (non-covered item or service).

▼ HCPCS Level II Codes and Description

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.

E2402	Negative pressure wound therapy electrical pump, stationary or portable
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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
A9272	Mechanical Wound Suction. Disposable. Includes dressing, all accessories and components, each
K0743	Suction pump, home model, portable, for use on wounds
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches or less.
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches.
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 inches

The medical necessity for use of a greater quantity of supplies than the amounts listed must be clearly documented in the Member's medical record and submitted with claim. If this documentation is not present, excess quantities will be denied.

DOCUMENTATION REQUIREMENTS

Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.

The Affordable Care Act (ACA) 6407 requires that the treating physician conduct a face-to-face examination during the six month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

Documentation of the history, previous treatment regimens (if applicable), and current wound management for which a NPWT pump is being billed must be present in the member'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 member's medical record, must indicate regular evaluation and treatment of the member'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 provider must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the member's medical record, in order to determine whether the equipment and supplies continue to qualify for coverage. The supplier need not view the medical records in order to bill for continued use of NPWT. Whether the provider ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the provider. However, the member's medical records may be requested in order to corroborate that wound healing is/was occurring as represented on the provider's claims for reimbursement.

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 by forwarding supporting documentation and the special circumstances necessitating the extended therapy time to the Northwood Case Review Department / Physician reviewer for evaluation and action. (Send to Health Plan if designated).

▼ Staging Definitions

The staging of pressure ulcers used in this policy is as follows per the NPUAP guidelines 2016 Revision:

Definition: A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors is yet to be elucidated.

Stage 1 – Pressure Injury- Non-blanchable erythema of intact skin.

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

Stage 2 – Pressure Injury – Partial thickness skin loss with exposed dermis.

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

Stage 3 – Pressure Injury – Full thickness skin loss.

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

Stage 4 - Pressure Injury - Full thickness skin and tissue loss.

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Unstageable Pressure Injury – Obscured full-thickness skin and tissue loss.

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

Deep Tissue Pressure Injury- Persistent non-blanchable deep red, maroon or purple discoloration.

Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue,

subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury.

▼ Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

▼ References

Centers for Medicare and Medicaid Services, LCD NPUAP (National Pressure Ulcer Advisory Panel), 2016 Revision. Staging of Pressure Ulcers 2016.

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; October 2015

CGS Administrators, LLC. Jurisdiction B DME MAC, Negative Pressure Wound Therapy Pumps. Local Coverage Determination No. L33821; revised date October 1, 2015.

Noridian Healthcare Solutions, LLC. Jurisdiction A DME MAC, Negative Pressure Wound Therapy Pumps. Local Coverage Determination No. L33821; revised October 1, 2015.

Applicable URAC Standard

Core 8	Staff operational tools and support
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Change/Authorization History

Revision Number	Date	Description of Change	Prepared/Revised by	Approved by	Review Date:
A	Nov.2006	Initial Release	Rosanne Brugnioni	Ken Fasse	n/a
01	July2007	NPWT definition re-written. Staging guidelines updated per NPUAP. Healing guidelines updated. Surgical/traumatic wound guideline added.	Susan Glomb	Ken Fasse	
02		Annual review / no revisions	Susan Glomb	Ken Fasse	Dec.2008
03	Dec. 4, 2009	Annual review. Updated coding guidelines.	Susan Glomb	Ken Fasse	Dec. 2009
04	Aug.18, 2010	Policy review. Updates added.	Susan Glomb	Ken Fasse	
05	12-03-10	Annual Review – No changes	Susan Glomb	Ken Fasse	Dec.2010
06	07-05-11	Policy updated to show new K codes for wound suction pumps and associated dressings- coding guidelines.	Susan Glomb	Ken Fasse	
07	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri	
08	12-13-11	Annual Review. Added References to Policy	Susan Glomb	Dr. B. Almasri	Dec. 2011
09	11-28-12	Annual review – no changes.	Susan Glomb	Dr. B. Almasri	Nov. 2012

10	11-30-12	Added code A9272. Mechanical wound suction, disposable, includes dressing, all accessories and components, each. NOTE: Disposable wound suction pumps and related supplies are considered not reasonable and necessary because they do not meet the definition of DME.	Susan Glomb	Dr. B. Almasri	
11	12-18-13	Annual review. No changes	Susan Glomb	Dr. B. Almasri	
12	12-8-14	Annual Review. Added Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements .	Susan Glomb	Dr. B. Almasri	
13	12-3-15	Annual Review. Updated References	Susan Glomb	Dr. B. Almasri	
14	12-06-16	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016
15	03-27-17	Policy Updated per CMS LCD. Staging of Pressure Ulcers updated.	Susan Glomb	Dr. C. Lerchin	
16	12-20-17	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2017
17	12-03-18	Annual Review. Updated Medicare references.	Lisa Wojno	Dr. C. Lerchin	December 2018

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