Medical Coverage Policy

Negative Pressure Wound Therapy

☐ Device/Equipment ☐ Drug ☒ Medical ☐ Surgery ☐ Test ☐ Other

Effective Date:	2/26/2004	Policy Last Updated:	6/27/2011

☒ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☐ **Prospective review is not required.**

Description:
Negative pressure wound therapy or NPWT (also known as vacuum-assisted closure) uses a vacuum pump to assist in closing large wounds and wound areas that have had delayed progress in healing. The device attaches to the surface of the wound area with a special dressing. The negative pressure accelerates the healing process by drawing blood flow, clotting factors, and wound drainage to the surface of the wound.

Wounds are often categorized according to severity, into four stages:

Stage I: Skin intact but appears red for greater than one hour following relief of pressure
Stage II: Skin is injured with blister (broken or unbroken); with or without infection
Stage III: Subcutaneous destruction into muscle; with or without infection
Stage IV: Deepest injury (usually extending into the muscle, tendon or even bone); with or without infection

For purposes of this policy, a licensed health care professional 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.

Medical Criteria:
Negative pressure wound therapy is covered for the first 45 days without prior authorization. Prior authorization is required/recommended for use beyond the initial 45 days.

For coverage beyond the initial 45 days, the following medical criteria must be met:

A. Ulcers and Wounds in the Home Setting:

When the patient has any of the following
- **a)** Chronic Stage III or IV pressure ulcer (see Appendices Section); **or**
- **b)** Neuropathic (for example, diabetic) ulcer; **or**
- **c)** Venous or arterial insufficiency ulcer; **or**
- d) Chronic (being present for at least 30 days) ulcer of mixed etiology.
- e) Traumatic or surgical wounds where there has been a failure of immediate or delayed primary closure AND there is exposed bone, cartilage, tendon, or foreign material within the wound AND no contraindications to use are present.

f) 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 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.

Listed below are specific types of ulcers or wounds and their associated criteria:

2. The patient has Stage III or IV pressure ulcers:
   a) Has been appropriately turned and positioned; and
   b) Has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see DMERC medical policy on support surfaces), (a group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis); and Moisture and incontinence have been appropriately managed.

3. The patient has neuropathic (for example, diabetic) ulcers:
   a) 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. In order for coverage to continue for wounds and ulcers once placed on an NPWT pump and supplies, 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,
   a) document changes in the ulcer's dimensions and characteristics.

If criteria listed above are not fulfilled, continued coverage of the NPWT pump and supplies **will be denied as not medically necessary.**

C. For wounds and ulcers described above, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:

Criteria B1-B2 ceases to occur, when:

- In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
- 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.
- Four (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.

- Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

Continuation of services:

Continuation of the powered NPWT system, as part of a comprehensive wound care program, may be considered **medically necessary** following an initial 2-week therapeutic trial or a subsequent treatment period if the treatment has resulted in documented objective improvements in the wound. Objective improvements in the wound should include the development and presence of healthy granulation tissue, progressive wound contracture and decreasing depth, and/or the commencement of epithelial spread from the wound margins.

Continuation of the powered NPWT system is considered **not medically necessary** when any of the following occurs:

- The therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound, OR
- The wound has developed evidence of wound complications contraindicating continued NPWT, OR
- The wound has healed to an extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments.

Not Medically Necessary:
A NPWT pump and supplies will be denied at any time as **not medically 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;
- 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.

Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above are considered **not medically necessary**.

Use of non-powered NPWT systems for the treatment of acute or chronic wounds is **not medically necessary**.

Supplies:
Payment 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.

Payment 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. Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) will be denied as not medically necessary.

The medical necessity for use of a greater quantity of supplies than the amounts listed must be clearly documented in the patient's medical record and may be requested by the contracted DME provider for Medicare. If this documentation is not present, excess quantities will be denied for lack of medical necessity.

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.

Other exclusions from coverage:

NPWT pumps and their supplies, which have not been specifically designated as being qualified for use of HCPCS code E2402 for billing to the contracted DME provider for Medicare, will be denied as not medically necessary.

Policy:
Medical review is required is required for BlueCHiP for Medicare and recommended for all other lines of business after 45 day days.

Negative pressure wound therapy is a covered service for all product lines when the criteria listed above has been met.

Once the service has been approved over 45 days, thereafter it will be re-reviewed every 30 days.

Coverage:
Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage, subscriber agreement, or Benefit Booklet for the applicable Medical Equipment, Medical Supplies, and Prosthetic Devices benefit/coverage.

Concurrent use of Hyperbaric Oxygen Therapy (HBO) and Vacuum-Assisted Wound Closure: see hyperbaric oxygen therapy medical policy for clinical indications. Coverage is based on limited criteria and medical review is needed for this service.

Coding:
97605
97606
E2402

Reimbursement of vacuum-assisted wound closure (VAC) is under the DME benefit and based upon a daily rate, which will include a maximum of 15 canisters and 25 standard dressing sets per 30-day period. Dressing kits and drainage canisters (A6550) are inclusive in the global fee and are non-billable to the member and the Plan. Requests for reimbursement of additional supplies will require medical necessity review.

Effective July 1, 2011, the following codes are covered:
K0743
K0744
K0745
K0746

Also Known As:
Wound Vac
Vacuum Assisted Wound Closure
Negative Pressure Wound Therapy

Related Topics:
Not applicable

Published:
Policy Update, May, 2004
Policy Update, October, 2005
Policy Update, September, 2006
Provider Update, February 2009
Provider Update, December 2010
Provider Update, September 2011

References:

Bello YM, Phillips TJ. Recent Advances in Wound Healing. JAMA;2000:283:6.

Blue Cross Blue Shield Association Medical Policy Reference. Policy 1.01.16 - Negative Pressure Wound Therapy in the Outpatient Setting. Reviewed with literature search/April 2010.

CMS. MM7411 – New K Codes for Suction Pumps and Wound Dressings. Reference: http://www.cms.gov/MLNMattersArticles/Downloads/MM7411.pdf.

Gottrup F, Holstein P, Jorgensen B, Lohmann M, Karlsmark T. A New Concept of a Multidisciplinary WEound Healing Center and a National Expert Function of Wound Healing. Arch Surg;2001:136:765-772. Reference: www.archsurg.com.

Mendez-Eastman S. New treatment for an old problem: negative-pressure. Nursing;May 2002;32:5:58-63.

MLN Matters. Transmittal number: R2206CP;Effective Date: July 1, 2011.

Sampson DJ, Lefevre F, Aronson N. Wound-healing technologies: low-level laser and vacuum-assisted closure. Evidence Report/Technology Assessment:111. Reference: www.ahrq.gov.

Scherer LA, Shiver S, Chang M, Meredith JW, Owings JT. The Vacuum Assisted Closure Device. A Method of Securing Skin Grafts and Improving Graft Surival. Arch Surg;2002:137:930-934. Reference: www.archsurg.com.

Shirakawa M, Isseroff R; Arch. Topical negative pressure devices. Use for enhancement of healing chronic wounds. Dermatology;2005:141:1449-53.