



BlueShield
of Northeastern New York

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Protocol

Negative Pressure Wound Therapy (NPWT) Pump (Chronic or Acute Wounds) (Formerly Negative Pressure Wound Therapy)

Effective May 1, 2005

Contracts Affected:
All Community Blue HMO
*****Senior Blue/Medicare PPO**
Traditional Blue

*The following protocol contains medical necessity criteria for Negative Pressure Wound Therapy (NPWT) Pump services rendered on or May 1, 2005 for BlueShield of Northeastern New York (BlueShield) contracts. If these criteria are not met, reimbursement will be denied and the patient cannot be billed. **Prior approval is required.** Please note that payment for covered services is subject to the limitations noted in the above-referenced contracts and the patient's eligibility at the time the services are rendered.*

Description

The management and treatment of chronic wounds, including decubitus ulcers, remain a treatment challenge. Most chronic wounds will heal only if the underlying cause, i.e., venous stasis, pressure, infection, etc., is addressed. In addition, cleaning the wound to remove non-viable tissue, micro-organisms, and foreign bodies is essential to create the optimal conditions for either re-epithelialization (i.e., healing by secondary intention) or preparation for wound closure with skin grafts or flaps (i.e., healing by primary intention). Therefore, debridement, irrigation, whirlpool treatments, and wet-to-dry dressings are common components of chronic wound care.

Negative wound pressure therapy (NPWT) consists of the use of a negative pressure therapy or suction device to aspirate and remove fluids, debris, and infectious materials and debris from the wound bed to promote the formation of granulation tissue. The devices may be used as an adjunct to surgical therapy, or as an alternative to surgery in a debilitated patient. Although the exact mechanism has not been elucidated, it is hypothesized that negative pressure contributes to wound healing by removing excess interstitial fluid, increasing the vascularity of the wound, and/or creating beneficial mechanical forces that draw the edges of the wound closer together.

Negative pressure therapy or suction devices cleared by the U.S. Food and Drug Administration (FDA) for the purpose of treating chronic wounds include, but are not limited to:

- V.A.C.® (Negative pressure therapy Assisted Closure®) Therapy™ (Kinetic Concepts, Inc); and
- Versatile 1 Wound Negative pressure therapy System (Blue Sky Medical).

Corporate Medical Guideline

Negative Pressure Wound Therapy is **medically appropriate** for the following conditions when the patient has adequate nutrition for healing, and there is a moist wound environment for 2 weeks or more without progression of wound healing:

- Stage III/IV pressure ulcer (when incontinence does not exist and there has been a 2 week or more failed trial of a pressure reducing support surface, if appropriate)
- Diabetic ulcer (when nonweight-bearing/pressure reductions interventions have been tried for 2 weeks or more without signs of healing and the patient has participated in a comprehensive diabetes management program which includes continuous education and periodic assessment)

- Venous Ulcer (when use of a compression/garment dressing has been unsuccessful for 2 or more weeks)
- Arterial ulcer
- Chronic ulcer/wound (which has existed for 30 days or more)

NPWT is **medically appropriate** to treat an acute or traumatic wound when there is no evidence of healing after 1 week and there are pre-existing systemic conditions such as collagen vascular disease, diabetes mellitus, immune deficiencies, impaired nutrition, malignancy, peripheral arterial disease, peripheral neuropathy or psychosis/depression.

NPWT is **medically appropriate** applied intraoperatively for a post split thickness skin graft which is over a bony prominence, joint or uneven surface.

In all medically appropriate applications, there needs to be:

- Documented wound healing;
- Documented need for continued NPWT; and
- Use no longer than 4 months.

NPWT should be discontinued when the wound is healed as evidenced by a thin area of “new” epidermis, adequate healing has occurred in the opinion of the medical professional, or progression of wound healing has failed to occur over 4 weeks. If a wound has failed to heal after 4 months of therapy, including any inpatient use, requests for further therapy will require individual review by a Medical Director.

*** Senior Blue/Medicare PPO ***

For Senior Blue/Medicare PPO an NPWT pump and supplies are **medically appropriate** when either criterion A or B is met:

A) Ulcers and Wounds in the Home Setting:

The patient has a chronic Stage III or IV pressure ulcer*, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

1. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:
 - a. Documentation in the patient’s medical record of evaluation, care, and wound measurements by a licensed medical professional,
 - b. Application of dressings to maintain a moist wound environment,
 - c. Debridement of necrotic tissue if present, and
 - d. Evaluation of and provision for adequate nutritional status.
2. For Stage III or IV pressure ulcers:
 - a. The patient has been appropriately turned and positioned,
 - b. The patient has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see LCDs on support surfaces), and
 - c. The patient’s moisture and incontinence have been appropriately managed.
3. For neuropathic (for example, diabetic) ulcers:
 - a. The patient has been on a comprehensive diabetic management program, and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.

4. For venous insufficiency ulcers:
 - a. Compression bandages and/or garments have been consistently applied, and
 - b. Leg elevation and ambulation have been encouraged.

B) Ulcers and Wounds Encountered in an Inpatient Setting:

1. An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating physician, the best available treatment option.
2. The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments).

In either situation B-1 or B-2, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting.

If criterion A or B above is not met, the NPWT pump and supplies will be denied as **not medically necessary**.

NPWT pumps need to be capable of accommodating more than one wound dressing set in the case when the patient has multiple wounds. In other words, it would be **not medically appropriate** for more than one NPWT at a time.

An NPWT pump and supplies are **not medically appropriate** 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; and
- The presence of a fistula to an organ or body cavity within the vicinity of the wound.

C) Continued medical appropriateness: For wounds and ulcers described under A or B above, once placed on an NPWT pump and supplies, in order to continue to be considered **medically appropriate** continue a licensed medical professional must do the following:

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

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

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

- A) Criteria C1-C2 cease to occur,
- B) In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
- C) 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,
- D) 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, and
- E) Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

It is usually **not medically necessary** to need more than 15 dressing kits per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.

It is usually **not medically necessary** to need more than 10 canister sets 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, it is **medically appropriate** to only use a stationary pump with the largest capacity canister.

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

Stage I - 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.

Stage II - Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.

Stage III - 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.

Stage IV - 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.

Prior approval is required. BlueShield fully expects that only appropriate and medically necessary services will be rendered. BlueShield reserves the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures.

References

1. NHIC DME MAC A, LCD for negative Pressure Wound Therapy Pumps, L11500, 7/1/07.
2. BlueCross BlueShield Negative Pressure Therapy for the Treatment of Chronic Wounds 1.01.16, 12/12/06.
3. McKesson Interqual^R SmartSheetTM, Negative Pressure Wound Therapy (NPWT) Pump: General 2007.

Last Review Date

Reviewed with literature search/November 2007

Next Review Date

Review with literature search/November 2008