

Medical Affairs Policy & Procedure

Title/Service: Negative Pressure Wound Therapy (NPWT) Pump

Revised	
Reviewed	08/25/00, 06/17/03, 07/22/05, 08/25/06, 05/18/07, 05/16/08, 12/29/08, 07/27/10, 09/16/2011
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Description:

Negative pressure wound therapy 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. The dressing includes a resilient, open-cell foam surface dressing, sealed with an occlusive dressing that is meant to contain the subatmospheric pressure at the wound site. The use of NPWT may assist in the treatment of the wound by helping to remove fluid from the wound, increase local blood flow, decrease bacterial growth, and increase the growth of granulation tissue (tissue covering the wound).

Indications of Coverage:

The NPWT pump and supplies are considered medically necessary for the treatment of a chronic stage III or IV pressure ulcers, chronic diabetic ulcers, or chronic arterial or venous insufficiency ulcers when the following criteria for prior treatment and those related to the specific ulcer type are met:

- A. There has been a lack of progress in wound healing with prior treatment despite a minimum of thirty days participation in a wound therapy program that includes the following:
 1. Weekly visits with written documentation of evaluation and care by a licensed medical professional that includes all of the following:
 2. Documentation of the wound's measurements
 3. Application of moist topical dressings
 4. Serial sharp, chemical, and/or mechanical debridement of necrotic tissue as appropriate
 5. Evaluation of adequate nutritional status as documented by a serum albumin greater than 3.0g/dl during the month prior to use of the NPWT pump.

B. Stage III or IV pressure ulcer – the ulcer remains a full thickness wound, despite the consistent application of **all** of the following additional measures, for at least the last two continuous months prior to initiating use of an NPWT pump:

1. The individual has been appropriately turned and positioned
2. The individual has used appropriate pressure relief devices (for example, alternating pressure mattress)
3. The individual's moisture and incontinence have been appropriately managed

C. Chronic diabetic ulcer - the ulcer has demonstrated lack of improvement, despite the consistent application of all of the following additional measures, for at least the last two continuous months prior to initiating use of an NPWT pump:

1. The individual has been on a comprehensive diabetic management program
2. The individual has had appropriate foot care
3. The individual has been non-weight bearing as appropriate.

D. Chronic arterial or venous ulcer - the ulcer has demonstrated lack of improvement, despite the consistent application of all of the following additional measures, for at least the last two continuous months prior to initiating use of an NPWT pump:

1. Compression garments/dressings have been consistently applied
2. Leg elevation has been encouraged

The NPWT pump and supplies are considered medically necessary for the treatment of complications of a surgically created wound (for example, dehiscence or disunion of a sternotomy or abdominal wall incision) or a traumatic wound (for example, preoperative flap or graft or exposed bones, tissue, vasculature) 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).

- If criteria are met, NPWT can be allowed for a maximum of four months. Continued use of NPWT will be allowed only when the criteria listed above continues to be met and the medical record documents clear improvement from the current and previous use of NPWT.

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. The NPWT pump and supplies are considered not medically necessary when any of the following are documented:
 - The presence of necrotic tissue with eschar (scab) in the wound
 - 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

Documentation Required:

- Office notes
- Documentation from the wound therapy program
- A written order for the NPWT pump and supplies

Rationale:

The use of wound therapy pumps has been advocated for those individuals with wounds that have not responded to standard wound care. There are limited controlled clinical trials evaluating the effectiveness of vacuum-assisted wound therapy; however, the few published studies that are available do document some improvement in healing when the wound therapy pump is used for certain conditions. Most of the other literature evaluates a small number of individuals and does not include a control group using standard wound therapy only. Therefore, the appropriateness of vacuum-assisted wound therapy for any condition has not been definitively established.

The Centers for Medicare and Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ) recently commissioned a review of NPWT devices. The resulting report noted significant limitations in the evidence regarding NPWT devices, such as the lack of quality clinical evidence supporting the advantages of NPWT compared to other wound treatments, the lack of studies comparing different NPWT

components (for example, foam dressings and gauze dressings), and the lack of studies evaluating the effectiveness of NPWT for various wound types.

References:

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3. Orgill DP, Bayer LR. Update on negative-pressure wound therapy. *Plast Reconstr Surg*. 2011 Jan;127 Suppl 1:105S-115S.
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6. Stevens P. Vacuum-assisted closure of laparostomy wounds: a critical review of the literature. *Int Wound J*. 2009 Aug;6(4):259-66.

Approved by the Medical Director