

Corporate Medical Policy

Topical Negative Pressure Therapy for Wounds

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Description of Procedure or Service

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, microorganisms, 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 pressure wound therapy (NPWT) consists of the use of a negative pressure therapy or suction device to aspirate and remove fluids, debris, and infectious materials 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.

A non-powered (mechanical) NPWT system has also been developed; one device is the Smart Negative Pressure (SNaP) Wound Care System. This device is portable and lightweight (3 oz) and can be worn underneath clothing. This system consists of a cartridge, dressing, and strap; the cartridge acts as the negative pressure source. The system is reported to generate negative pressure levels similar to other NPWT systems. This system is fully disposable.

The focus of this document is on use of NPWT in the outpatient setting.

Regulatory Status

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); Versatile 1™ Wound Negative pressure therapy System (Blue Sky Medical), and RENASYS EZ and RENASYS GO systems (The latter is a portable system) (Smith-Nephew).

A non-powered NPWT device, the SNaP Wound Care System from Spiracur, is a Class II device requiring notification to market but not having FDA premarket approval. It received 510(k) marketing clearance from the FDA in 2009 (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, subacute wounds and diabetic and pressure ulcers. No NPWT device has been cleared for use in infants and children.

In November 2009, the FDA issued an alert concerning complications and deaths that had been associated with negative pressure wound therapy systems.

(<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm>.)

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Policy

BCBSNC will provide coverage for Topical Negative Pressure Therapy for Wounds when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

See Other Services for Durable Medical Equipment (DME). Depending on specific contracts, coverage for the components (pump, canisters, dressings) of a topical negative pressure therapy system for wounds is processed under DME.

DME Supplier must meet eligibility and/or credentialing requirements as defined by the Plan in order to be eligible for reimbursement.

The individual certificate should be reviewed to verify eligibility requirements and any prior review necessary for the rental/purchase of equipment.

When Topical Negative Pressure Therapy for Wounds is covered

Initiation of a Powered Negative Pressure Wound Therapy (NPWT):

An initial 2-week therapeutic trial using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling factors such as diabetes, nutrition, relief of pressure, etc., may be considered medically necessary in the following indications:

- Chronic (> 90 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care when:
 - high-volume drainage interferes with healing; OR
 - standard dressings cannot be maintained due to anatomic factors.
- Non-healing wounds in patients with underlying clinical conditions which are known to negatively impact wound healing. Wound must have failed to heal despite optimal wound care for at least 30 days. Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the negative pressure wound therapy.
- Traumatic or surgical wounds with:
 - failure of immediate or delayed primary closure; AND
 - exposed bone, cartilage, tendon, or foreign material within the wound; AND
 - no contraindications to negative pressure wound therapy (see Policy Guidelines).
- Enterocutaneous fistulas.

Continuation of a Powered NPWT:

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.

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When Topical Negative Pressure Therapy for Wounds is not covered

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.

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 considered investigational.

Policy Guidelines

Contraindications to the use of NPWT systems include the following conditions as noted by a November 2009 FDA alert: necrotic tissue with eschar, untreated osteomyelitis, nonenteric and unexplored fistulas, malignancy in the wound, exposed nerve, exposed anastomotic site, and exposed organ.

NPWT systems should be used with caution in the following:

- Active bleeding or at high risk for bleeding and hemorrhage
- Patients on anticoagulants or platelet aggregation inhibitors
- Difficult wound hemostasis
- When placing the dressing in proximity to blood vessels, care should be taken to ensure that all vessels are adequately protected with overlying fascia, tissue or other protective barrier. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels
- Infected wounds
- Osteomyelitis
- Sharp edges in the wounds (i.e., bone fragments)
- Spinal cord injury (stimulation of sympathetic nervous system)
- Enteric fistulas

Continuation of healing during use of the NPWT system should be monitored on a frequency not less than every 14 days.

Complete healing of a wound would normally be anticipated if all bone, cartilage, tendons, and foreign material were completely covered, healthy granulation were present to within 5 mm of the surface, and the wound edges were reduced to 2 cm in width or diameter.

Powered negative pressure therapy systems should be used as part of a comprehensive wound care program that includes attention to other factors that impact wound healing such as diabetes control, nutritional status, relief of pressure, etc.

The focus of these policy statements and guidelines is for use of NPWT in the outpatient setting.

Rationale:

Anecdotal and limited clinical trials demonstrate that there is a subset of problematic wounds where the use of negative pressure wound therapy (NPWT) may provide a significant clinical benefit. However, due to clinical variability and the limited data, it is not possible to determine prospectively which wounds

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are most likely to respond favorably to NPWT. Therefore, the policy statement indicates that a therapeutic trial of NPWT of not less than 14 days may be considered medically necessary for acute and chronic wounds with either demonstrated failure to heal despite intense conventional wound therapy for 90 days or more, or for those wounds that have a high probability of failure to heal due to compounding factors involving the wound and the patient. Continued use of NPWT requires objective evidence of wound healing such as the development of healthy granulation tissue and progressive wound contracture.

Use of NPWT for other wounds may be considered not medically necessary as these wounds will heal through conventional wound management, i.e., the evidence does not demonstrate an incremental improvement in wound healing with use of the NPWT for these cases.

Reports with small numbers of patients, including planned interim analysis of a comparative trial, using the non-powered (mechanical) gauze-based NPWT system are insufficient to draw conclusions about its impact on net health outcome, both for the device itself and in comparison with current care. There are important unanswered questions about efficacy and tolerability. Well-designed comparative studies with large numbers of patients are needed. Since the impact on net health outcome compared to existing technology is not known, this is considered investigational.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 97605, 97606, A6550, A7000, A7001, A9272, E2402, K0743, K0744, K0745, K0746

The following information may be requested for review of medical necessity:

1. Type and age of wound and any prior treatment
2. Patient compliance with therapies
3. Size of wound and amount of drainage
4. Comorbid conditions
5. Nutritional status
6. Medical records documenting complete wound therapy program (refer to Policy Guidelines for details)
7. Treatment plan stating specific functional goals and estimating when those goals will be reached.
8. Operative note or wound care notes, if request is for use of topical negative pressure therapy in surgical and/or traumatic wounds.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual - 1/30/98

Medical Policy Advisory Group - 10/99

Specialty Matched Consultant Advisory Panel - 9/2000

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

Medicare DMERC Medical Policy for Negative Pressure Wound Therapy Pumps

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- ECRI Target™ Fact Sheet on Vacuum-Assisted Closure Therapy for Wound Healing; April, 2000
- ECRI Windows on Medical Technology™ for Vacuum-Assisted Wound Closure for Chronic and Acute Wounds; October, 2000
- BCBSA Medical Policy Reference Manual - Policy 1.01.16 - 7/12/02
- Specialty Matched Consultant Advisory Panel - 8/2002
- BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.16, 10/9/03.
- Specialty Matched Consultant Advisory Panel - 8/2004
- Cro, C., George, K.J., et al. Vacuum assisted closure system in the management of enterocutaneous fistulae, *Postgrad Med J*, June 2002; 78(920): 364-5.
- Erdmann Detlev, Drye Carol, et al. Abdominal wall defect and enterocutaneous fistula treatment with the vacuum-assisted closure (V.A.C.) system, *Plastic and Reconstructive Surgery*, December 2001, pp.2066-2068.
- Goverman J, Yelon JA, Platz JJ, Singson RC, & Turcinovic M. The "Fistula VAC," a technique for management of enterocutaneous fistulae arising within the open abdomen: report of 5 cases. *J Trauma*. 2006 Feb;60(2):428-31.
- Specialty Matched Consultant Advisory Panel - 8/2006
- The V.A.C. (Vacuum Assisted Closure) Clinical Guidelines. KCI, Inc., December 2006.
- Specialty Matched Consultant Advisory Panel - 9/4/2008
- Negative Pressure Wound Therapy. Technology Assessment. November 2009. Rockville, MD: Agency for Healthcare Research and Quality. <http://www.ahrq.gov/clinic/ta/negpresswtd/>. Retrieved 7/23/2010
- National Institute for Health and Clinical Excellence (NICE). Negative pressure wound therapy for the open abdomen. *Interventional Procedure Guidance 322*. London, UK: NICE; December 2009
- BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.16, 4/8/2010

Policy Implementation/Update Information

From policy entitled: Vacuum-Assisted Closure of Wounds:

- 12/98 New Policy Issued, based on BCBSA policy.
- There is minimal published data regarding vacuum-assisted closure of wounds, consisting of one animal study and an uncontrolled case series of 300 patients. Controlled trials are needed to demonstrate the independent contribution of vacuum-assisted closure to the overall management of chronic wounds.
- 7/99 Reformatted, Medical Term Definitions added.
- 10/99 Medical Policy Advisory Group
- 10/00 Sent to two Specialty Matched Consultant Advisory Panels. No change recommended in criteria. Medical Policy Advisory Group review. No change recommended in criteria. Approve.
- 2/02 Coding format change.
- 9/02 Specialty Matched Consultant Advisory Panel review 8/2002. Policy revised from investigational to covered in specific conditions. Name changed from "Vacuum Assisted Closure of Chronic Wounds" to "Vacuum Assisted Closure of Wounds". Codes K0538, K0539 and K0540 added to Billing/Coding section. System coding changes.

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- 10/02 System coding changes.
- 6/03 Policy Reformatted. Additional information added to "Description" section. "When covered" now includes A., B. and C. with types of wounds listed. "Policy Guidelines" now has two major requirements for complete wound therapy program-1) General measures and 2) Therapy specific to type of wound.
- 10/28/04 Specialty Matched Consultant Advisory Panel review. Additional information added and criteria changes made regarding acute and subacute wounds. Removed codes K0538, K0539, and K0540 from the policy. They were deleted 1/1/04. Notification given 10/28/04. Effective date of policy is 1/6/2005.
- 01/06/05 Added 2005 CPT codes 97605 and 97606 to Billing/Coding section. Billing/Coding section updated for consistency.
- 1/5/06 Removed deleted code A6551 from Billing/Coding section.
- 4/24/06 Under Policy Guidelines section, first sentence, clarified that the complete wound therapy program should be documented in the medical records: "A complete wound therapy program *documented in medical records should* include both of the following criteria....." Same section, 2.D.i. last sentence, also clarified the records that should contain documentation for medical necessity: "Necessity for a wound vac in surgical and/or traumatic wounds must be clearly documented in the *operative note or wound care notes or records* by a statement...." The italicized wording has also been added under When not Covered section, 3.a. re: acute or subacute wounds. Similar information added to Billing/Coding/Physician Documentation Information.
- 5/21/07 Under "**When not Covered**" section: added the following to #1; e. The skin surrounding the wound does not allow for an effective adhesive drape necessary to create negative pressure; **or** f. The wound is a Stage I or II pressure ulcer, **or** g. A measurable degree of wound healing has failed to occur after use of the vacuum-assisted closure device for one month; **or** f. Adequate wound healing has occurred to the degree that use of the vacuum-assisted closure device may be discontinued (uniform granulation tissue has been obtained).
- Under "**Policy Guidelines**" added the following: Vacuum-assisted closure is used to initiate the healing of wounds. It is a technique designed to promote the formation of granulation tissue in the wound bed either as an adjunct to surgical therapy, or as an alternative to surgery in a debilitated patient. Vacuum-assisted closure can create optimal conditions for either reepithelialization (e.g., healing by secondary intention) or preparation for wound closure with skin grafts, or flaps (e.g., healing by primary intention). Added A. **Chronic wounds**: Medical records should document that a complete wound therapy program has been attempted and that progressive wound healing has failed to occur after 30 days. A complete wound therapy program should include both 1 and 2 of the following criteria (depending on the type of wound).....A.1. deleted end of sentence, "which should be addressed, applied, or considered and ruled out prior to application of vacuum assisted closure..." Acute and subacute wounds are now B.1-B.5. as follows: 1. (new) The patient has complications of a surgically-created wound including, but not limited to, post-sternotomy disunion with exposed sternal bone, post-sternotomy mediastinitis, postoperative disunion of the abdominal wall, flap or graft failure, dehisced wounds, A complicated surgical wound is a wound likely to take significantly longer to heal than a similar wound without complications, such as a large dehiscence. 2. (new) The patient has a traumatic wound that will require a flap or graft such as a degloving injury, high-energy soft tissue injury (falls, MVA, sports), wounds exposing tendons, bone and/or joint. The VAC may be used to help promote healing prior to a flap or graft by advancing early healing of the site and thereby helping to prepare the wound bed for a flap or graft procedure. VAC may also avoid local or free-tissue transfer in some instances. 3. (revised) There is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments. 4. (new) There is risk or co-morbidity present expected to significantly prolong healing achievable with other topical wound treatments. Patients with other medical problems (i.e.,

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diabetes, coronary artery disease, or renal disease) may be more susceptible to wound dehiscence and delayed wound healing. 5. was in last half of old d.i.-no changes. Re: last paragraph (not numbered), now reads: Vacuum-assisted closure may be considered medically necessary as long as the on-going wound care is performed or supervised by a licensed health care provider and there is at least biweekly documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth. The recorded wound measurements must demonstrate progressive wound healing between evaluations or after four weeks of vacuum-assisted wound therapy (including in-patient time) has evolved. The majority of patients achieve sufficient wound closure with six weeks of vacuum-assisted closure therapy; some patients may require longer. However, coverage beyond four months is generally considered not medically necessary. It is not necessary to continue using until a wound is completely healed. For example, if the depth of a wound is less than 0.5cm, then it would generally not be appropriate to continue use of the device. Also, if improvement of a wound has steadily occurred during four months treatment, then continued use on that wound would very rarely be medically necessary. An exception might be a very large open sternotomy or abdominal wound which had improved but was still quite large after four months of treatment.

Under Billing/Coding section, added: "Treatment plan stating specific functional goals and estimating when those goals will be reached."

Specialty Matched Consultant Advisory Panel review 8/2006. Under "When Covered" section, added criteria for enteric fistulas. Under "When not Covered" section; 1.a. now reads "The presence of non-enteric or unexplored fistulas within the vicinity of the wound." Reference sources added. (pmo)

10/6/08

Revisions under "When Covered" section:

B. Now reads "*Complications of a surgically created wound (e.g., dehiscence) or a traumatic wound (e.g., pre-operative flap or graft) when the following criteria are met. 1) Coverage may be provided only if a conventional wound therapy program has been tried and failed or if the patient has a contraindication to a conventional wound therapy program. Documentation must be provided (see Billing/Coding/Physician Documentation Information section). 2) Need for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments because of the unique nature of the wound. 3) There is risk or comorbidity present expected to significantly prolong healing achievable with other topical wound treatments.*"

Revisions under "When Not Covered" section:

3. Now reads "*Vacuum-Assisted Closure of surgically created wounds or traumatic wounds is not covered if the criteria under "When Covered" section, B.1-3 is not met.*"

Revisions under "Policy Guidelines" section:

B. ~~Surgically Created or Traumatic Acute and subacute Wounds:~~

1) Coverage may be provided only if a conventional wound therapy program has been tried and failed or if the patient has a contraindication to a conventional wound therapy program. Documentation must be provided. Vacuum-assisted closure ~~Wound vacs~~ will not be approved as primary treatment.

C. *Continued Coverage for Wounds Described Above:* Vacuum-assisted closure may be.....

Other:

Key words and Reference source added. "VAC" or "wound vac" have been replaced with "vacuum-assisted closure" throughout the policy.

Notification given 10/6/08. Effective date 1/5/09. (pmo)

Policy retitled: Topical Negative Pressure Therapy for Wounds

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- 1/5/09 Policy entitled "Vacuum Assisted Closure of Wounds" retitled to "Topical Negative Pressure Therapy for Wounds". The term "vacuum-assisted closure" has been replaced with "topical negative pressure therapy" throughout the policy. (pmo)
- 2/2/09 Under When Covered section, B., clarified that B.1. should have "and" at the end; B.2. should be B.1.a. and should have "or" at the end; and B.3. should be B.1.b. Will now read: "B. Complications of a surgically created wound (e.g., dehiscence) or a traumatic wound (e.g., pre-operative flap or graft) when the following criteria are met. 1. Coverage may be provided only if a conventional wound therapy program has been tried and failed or if the patient has a contraindication to a conventional wound therapy program. Documentation must be provided (see Billing/Coding/Physician Documentation Information section); **AND** a. There is a need for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments because of the unique nature of the wound; **OR** b. There is risk or co-morbidity present expected to significantly prolong healing achievable with other topical wound treatments. (pmo)
- 3/30/09 Key word section deleted. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 10/26/10 Description section revised. Policy statement unchanged. Coverage criteria reformatted and revised. An initial 2-week therapeutic trial using NPWT system, as part of a comprehensive wound care program that includes controlling factors such as diabetes, nutrition, relief of pressure, etc., may be considered medically necessary under the conditions noted in the policy. Continuation of the 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. Continuation of the NPWT system is considered Not Medically Necessary when the therapeutic trial or subsequent treatment period has not resulted in documented objection improvement in the wound, or the wound has developed evidence of 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. Therapeutic trials of NPWT systems for the treatment of other acute or chronic wounds except as noted above are considered not medically necessary. Policy Guidelines and References Updated. Notification given 10/26/10 for effective date of 2/01/2011. (adn)
- 12/20/11 Description section updated to include information on non-powered (mechanical) NPWT systems. Updated FDA link. The word "powered" was added to "NPWT" where applicable. The following statement was added to the When NPWT is Not Covered section: "Use of non-powered NPWT systems for the treatment of acute or chronic wounds is considered investigational." Codes A7000, A7001, A9272, K0743, K0744, K0745, K0746 added to Billing/Coding section. Noted in the Billing/Coding section that there is no specific code for the disposable NPWT system. Specialty Matched Consultant Advisory Panel review 11/30/11. (adn)
- 3/20/12 Removed the following statement from the Billing/Coding section as there is now a specific code (A9272) for a disposable NPWT system: "There are no specific codes for a disposable NPWT system. It may be coded using an unlisted code such as A4649". (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

