



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Vacuum-Assisted Closure of Chronic Wounds (Negative Pressure Wound Therapy)

Policy # 00132

Original Effective Date: 04/14/2003

Current Effective Date: 04/23/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider vacuum-assisted wound closure devices to be **eligible for coverage** when patient selection criteria are met.

Patient Selection Criteria

Initial Approval Criteria

Coverage eligibility will be considered when any of the following criteria are met:

- Stage III or IV chronic open wounds (diabetic or pressure ulcers) present for at least 30 days, and demonstrated failure of conventional wound treatment measures; or
- Stage III or IV chronic open wounds (diabetic or pressure ulcers) present for at least 30 days, and the use of conventional wound treatment measures has been considered and ruled out; or
- Other problematic wounds requiring the need for accelerated formation of granulation tissue that cannot be achieved by other available topical wound treatments, involving:
 - o Significant risk of infection, such as wound location
 - o Immunocompromised status
 - o Circulatory or metabolic compromise
 - o Failed conservative treatment
 - o Dehisced wounds of significant size

Medical record documentation must include all of the following:

- Direct wound evaluation, assessment and management based on standardized wound criteria are performed by an appropriately licensed medical professional. (Photograph and measurements are required for initial coverage requests); and
- At least monthly documentation of quantitative measurements of changes in wound/ulcer dimensions and characteristics, including surface area, depth, and serial observations (photographs are required for continuing coverage requests); and
- Absence of necrosis; and
- Wound management including the application of treatments that maintain a moist wound environment; and
- Comprehensive disease/condition-specific management programs that provide optimal wound healing environment; and

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- Assessment of and/or appropriate intervention to establish and maintain adequate nutritional status; and
- Clinical need for use of vacuum assisted wound closure device in a Stage III or IV or problematic wounds.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company may consider vacuum assisted wound closure devices for the treatment of wounds to be **not medically necessary** under any of the following conditions:

- Initial coverage criteria are not met; or
- There is presence of necrotic tissue with eschar, if debridement is not attempted; or
- Untreated osteomyelitis exists in the vicinity of the wound; or
- Cancer is present in the wound; or
- There is the presence of a fistula to an organ or body cavity within the vicinity.

Based on review of available data, the Company may consider vacuum assisted wound closure devices for the continuing treatment of wounds to be **not medically necessary** under any of the following conditions:

- Initial coverage criteria are no longer met; or
- In the judgment of the treating physician, adequate wound healing has occurred to the degree that the vacuum assisted wound care device can be discontinued; or
- Any measurable degree of wound healing has failed to occur over the prior 30 days; or
- The vacuum assisted wound closure device has been used for 60 days in the treatment of any wound. Coverage beyond 60 days will be given individual consideration based upon supplemental documentation.

Background/Overview

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.

Vacuum-assisted closure is 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. In this system, a special foam dressing with an attached evacuation tube is inserted into the wound and covered with an adhesive drape to create an airtight seal. Negative pressure is then applied and the wound effluent is collected in a canister. 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. Vacuum-assisted closure has also been referred to as “negative wound pressure therapy (NPWT)”.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Negative pressure therapy or suction devices cleared by the U.S. 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 NPWT systems. An updated alert was issued in February 2011. (Available online at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm>.)

Centers for Medicare and Medicaid Services (CMS)

In October 2000, Healthcare Financing Administration (HCFA; now Centers for Medicare and Medicaid Services, CMS) issued the following durable medical equipment regional carrier (DMERC) coverage policy, which stated that patients meeting the following criteria would be eligible for negative wound pressure therapy in the home setting:

Patient has a chronic Stage III or Stage IV pressure ulcer, venous or arterial insufficiency ulcer, or a chronic ulcer of mixed etiology. A complete wound therapy program should have been tried or considered and ruled out prior to application of negative pressure wound therapy.

Rationale/Source

Limited studies involving NPWT were identified in the literature. The available evidence regarding the safety and efficacy of NPWT to promote wound healing consisted of two randomized placebo-controlled trials, one nonrandomized controlled trial, seven prospective case series and five retrospective analyses. Small and heterogeneous patient populations, lack of blinding and insufficiently defined patient selection criteria and outcome measures compromised the quality of the evidence. Furthermore, Kinetic Concepts, Inc. (San Antonio, TX), the manufacturer of the only currently available NPWT devices, the vacuum-assisted wound closure (V.A.C.) systems, directly or indirectly funded at least six of these studies. Wake Forest University owns the patent, and the university and some of its investigators receive royalties from the sale of V.A.C. devices. Investigators at the Wake Forest University performed three of the studies that were evaluated for this health technology assessment.

The studies involved male and female patients with acute, subacute or chronic wounds. The patient populations were relatively small, ranging from 10 to 83 for most studies. One retrospective chart analysis included 1,262 patients (Philbeck et al., 1999), and one prospective case series included 300 patients. The

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study populations were heterogeneous with respect to age, duration of symptoms, and in most studies, also with respect to type and size of wound. In general, patients with the following types of wounds were evaluated:

Acute wounds

Acute donor sites, excised wounds, degloving injuries, deep abrasions, avulsions, gunshot wounds, eviscerations, nonosseous traumatic injury, traumatic amputation, burns

Subacute wounds

Dehiscence, infected and uninfected open wounds with exposed orthopedic hardware, postfemoral-popliteal bypass inguinal wound, skin graft failures, sternotomy infection following coronary artery bypass grafting

Chronic wounds

Pressure ulcers, venous stasis ulcers, cystic hidradenitis, and trauma- and radiation-related wounds

Treatment protocols also varied with respect to duration of treatment and subatmospheric pressures applied to the wound.

In general, subatmospheric pressures of 50 to 150mm Hg were used and pressure was applied continuously for 1 day to 6 weeks depending on the type of wound. Outpatients received a portable NPWT device to continue treatments at home. Dressing changes were performed every 48 hours in most studies. Outcome measures assessing the quality and rate of wound healing included:

- Granulation tissue formation;
- Changes in wound size;
- Incidence of complete or partial wound closure;
- Percentage of the extent of wound closure;
- Time to wound closure;
- Graft take;
- Re-epithelialization;
- Need for and success rates of additional procedures such as split-thickness skin grafting, flaps;
- Secondary closure;
- Duration of NPWT therapy;
- Bacterial load of infected wounds;
- Recurrence rates;
- Hospital length of stay;
- Quantitative assessment of inflammation;
- Adverse events.

Wound healing was assessed by clinical and histopathological examination, photographs, wound tracings and alginate impression molds. Bacterial load was assessed by bacterial cultures. Biopsies were taken and analyzed using light microscopy to assess degree of inflammation and granulation tissue formation as well as other histological changes.

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Evidence from the prospective case series and retrospective chart analysis indicates that while some patients failed treatment, NPWT generally enhanced wound closure in the majority of patients regardless of the type of wound, with closure rates ranging from 30% to 100%. NPWT increased granulation tissue formation, reduced tissue edema, increased the incidence of partial or complete wound closure, increased the incidence and percentage of graft take, downstage wounds allowing for lesser surgical procedures or primary closure, and decreased the time to healing. NPWT led to improved wound healing for selected cases with large, open, complex and/or infected wounds associated with exposed bone, tendon or viscera and obviated the need for surgical procedures in selected patients at high risk due to co-morbidities. However, not all wound types have been assessed in randomized controlled trials (RCTs).

The therapeutic benefits that were obtained in the uncontrolled studies were less pronounced in the RCTs, and the observed improvement of outcome measures did not reach statistical significance in one RCT. In this trial, NPWT reduced wound length, width and depth by 36.9cm, 40.0cm and 33.6cm, compared with 18.7cm, 19.0cm and 31.0cm in control group patients. The difference was not statistically significant; however, a significant reduction in the incidence of osteomyelitis was observed in patients treated with NPWT. However, in another RCT, NPWT significantly improved the reduction of wound depth, width and volume in patients with chronic wounds by 66%, 62% and 48%, respectively, compared with 20%, 35% and 39% in patients who received standard treatment. In addition, NPWT appeared to improve granulation tissue formation and reduced the incidence of complications (44%) compared with standard treatment (17%). Efficacy of NPWT for acute donor sites was also demonstrated in a nonrandomized controlled trial. In this trial, NPWT significantly increased re-epithelization rates in 70% of patients as compared with standard dressing.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Vacuum-Assisted Closure of Chronic Wounds (Negative Wound Pressure Therapy)", 1.01.16, 1:2014.
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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]†, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	97605, 97606
HCPCS	A6550, A7000, A7001, A7002, A9272, E2402, G0456, G0457, K0743, K0744, K0745, K0746
ICD-9 Diagnosis	All relevant diagnoses
ICD-9 Procedure	No codes

Policy History

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04/14/2003 Managed Care Advisory Council approval
01/31/2004 Medical Director review
02/17/2004 Medical Policy Committee review. Format revision. No substance change to policy.
02/23/2004 Managed Care Advisory Council approval
02/01/2005 Medical Director review
02/15/2005 Medical Policy Committee review
03/07/2005 Managed Care Advisory Council approval
03/09/2006 Medical Director review
03/15/2006 Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
04/05/2006 Medical Director review
04/19/2006 Medical Policy Committee approval
07/07/2006 Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged

03/14/2007 Medical Director review
03/21/2007 Medical Policy Committee approval. Coverage eligibility unchanged.
03/12/2008 Medical Director review
03/19/2008 Medical Policy Committee approval. Coverage eligibility unchanged.
04/02/2008 Medical Director review
04/16/2008 Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009 Medical Director review
04/15/2009 Medical Policy Committee approval. No change to coverage eligibility.
04/08/2010 Medical Director review
04/21/2010 Medical Policy Committee approval. No change to coverage eligibility.
04/07/2011 Medical Policy Committee review
04/13/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.
04/12/2012 Medical Policy Committee review

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04/25/2012 Medical Policy Implementation Committee approval. No change to coverage eligibility.

04/04/2013 Medical Policy Committee review

04/24/2013 Medical Policy Implementation Committee approval. No change to coverage eligibility.

04/03/2014 Medical Policy Committee review

04/23/2014 Medical Policy Implementation Committee approval. No change to coverage eligibility.

Next Scheduled Review Date: 04/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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