



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Negative Pressure Wound Therapy/Vacuum-Assisted Closure (VAC) for Nonhealing Wounds**

**Effective Date ..... 3/15/2009**  
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## Hyperlink to Related Coverage Policies

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- Noncontact Normothermic Wound Therapy (NNWT) (Warm-Up<sup>®</sup> Active Wound Therapy)
- Pneumatic Compression Devices for Vascular Diseases of the Lower Extremities
- Pressure Reducing Surfaces
- Pulsed Electromagnetic Stimulation
- Tissue-Engineered Skin Substitutes and Growth Factors
- Topical Hyperbaric Oxygen (THBO)Therapy)

## INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

## Coverage Policy

Coverage for negative pressure wound therapy/vacuum-assisted closure devices and accessories is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage is available for negative pressure wound therapy/vacuum-assisted closure and accessories, the following conditions of coverage apply.

CIGNA covers negative pressure wound therapy (NPWT)/vacuum-assisted closure (VAC) for nonhealing wounds as medically necessary when any ONE of the following conditions exists:

- There are complications of a surgically created wound (e.g., dehiscence, poststernotomy disunion with exposed sternal bone, poststernotomy mediastinitis, or postoperative disunion of the abdominal wall).
- There is a traumatic wound (e.g., preoperative flap or graft, exposed bones, tendons, or vessels) and a need for accelerated formation of granulation tissue not achievable by other topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments).
- There is a chronic, nonhealing ulcer with lack of improvement for at least the previous 30 days despite standard wound therapy, including the application of moist topical dressings, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, and weekly evaluations with documentation of wound measurements (i.e., length, width, and depth) in one of the following clinical situations:
  - Chronic Stage III or Stage IV pressure ulcer:
    - The individual has been on an appropriate turning and repositioning regimen.
    - The individual has used an appropriate pressure relief device (e.g., low air loss bed, alternating pressure mattress) for pressure ulcers on the posterior trunk or pelvis.
    - The individual's moisture and incontinence have been appropriately addressed.
  - Chronic diabetic neuropathic ulcer:
    - The individual has been on a comprehensive diabetic management program.
    - The individual has had appropriate foot care.
    - The individual has been nonweight bearing if appropriate.
  - Chronic venous ulcer:
    - Compression garments/dressings have been consistently applied.
    - Leg elevation and ambulation have been encouraged.

**CIGNA will cover medically necessary NPWT for up to four consecutive months, including any time during which NPWT was applied in an inpatient setting prior to discharge to home or a wound clinic. The use of NPWT beyond four months will be covered only when medical necessity continues to be met as previously outlined and there is evidence of clear benefit from the NPWT treatment already received.**

**CIGNA does not cover NPWT/VAC for nonhealing wounds or ulcers under ANY of the following conditions because it is considered not medically necessary (this list may not be all- inclusive):**

- An appropriate medical professional is not supervising or performing weekly wound measurement and assessment functions as well as the negative pressure wound therapy dressing changes required.
- Wound healing has occurred to the extent that negative pressure wound therapy is no longer necessary.
- The depth of the wound is less than 1 mm, as wounds of this depth cannot accommodate the sponge.
- Uniform granulation tissue has been obtained.
- The individual cannot tolerate the use of NPWT.
- The wound is infected.
- There is no progression of healing of the wound on two successive dressing changes.

## General Background

Chronic wounds, also known as ulcers, are wounds that have a biological or physiologic reason for not healing. Chronic wounds have not completed the process of healing in the expected period, or have proceeded through the healing phase without establishing the expected functional result. These wounds generally do not close without intervention and are sometimes unresponsive to healing interventions. Diabetic foot ulcers/sores, pressure ulcers or bed sores, venous leg ulcers, and sternal wound infections are all considered chronic wounds because their etiologies delay and prevent healing and they persist without proper medical care (ECRI, 2008).

There are numerous treatments that have been used to treat chronic wounds. They include: surgical debridement, surgical revascularization of the affected area, myocutaneous skin flaps or grafting, wet-to-dry dressings, NPWT, VAC, and the use of certain bioengineered skin substitutes. When clinically appropriate, all of

these interventions are used in combination with aggressive medical management of the underlying wound etiology (Stillman, 2008).

### **Chronic Wound Types**

**Pressure Ulcers:** A pressure ulcer is a result of pathologic changes in blood supply to the dermal and underlying tissues, usually because of compression of the tissue over a bony prominence. Chronic ulcers of the skin include arterial ulcers, venous stasis ulcers, diabetic ulcers, and pressure ulcers. Pressure ulcers generally appear in soft tissue over a bony prominence (Thomas, 2008).

Initial treatment for pressure ulcers is aimed at relieving pressure by positioning the patient frequently and at a fixed interval to relieve pressure over the compromised area. A number of medical devices, classified as static or dynamic, are designed to relieve pressure. Static devices include air, gel, or water-filled containers that reduce the tissue-to-surface contact. Dynamic devices use a power source to fill compartments with air that support the patient's weight or alternate the pressure on different areas of the body. It is suggested that patients who fail to improve, or who have multiple pressure ulcers, should be considered for a dynamic type device, such as a low air loss bed or air fluidized bed (Thomas, 2008).

Other treatment measures of pressure ulcers include treating pain; assessing nutrition and hydration; removing necrotic debris; maintaining a moist wound environment, which is associated with more rapid healing rates compared to dressings that are allowed to dry; encouraging granulation tissue formation and promoting re-epithelialization; and controlling infection (Thomas, 2008).

### **Staging of Pressure Ulcers**

When evaluating pressure ulcers, a staging system is typically used that measures tissue destruction by classifying wounds according to the tissue layers involved. In 2007, the National Pressure Ulcer Advisory Panel (NPUAP) redefined the definition of a pressure ulcer and the stages of pressure ulcers, including the original four stages and adding two stages on deep tissue injury and unstageable pressure ulcers. The stages are defined by the NPUAP as follows:

- Suspected Deep Tissue Injury: Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Further description: Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

- Stage I: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

Further description: The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons (a heralding sign of risk).

- Stage II: Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Further description: Presents as a shiny or dry shallow ulcer without slough or bruising. This stage should not be used to describe skin tears, tape burns, perineal dermatitis, maceration or excoriation. Bruising indicates suspected deep tissue injury.

- Stage III: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Further description: The depth of a stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

- Stage IV: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

Further description: The depth of a stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis possible. Exposed bone/tendon is visible or directly palpable.

- Unstageable: Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Further description: Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as "the body's natural (biological) cover" and should not be removed.

**Venous Stasis Ulcers:** Venous stasis occurs due to the incompetence of either the superficial or deep venous systems. Chronic venous ulcers are usually due to the incompetence of the deep venous system and are commonly painless. The consensus is unclear as to the exact pathophysiologic process that leads to ulceration and impaired healing with venous ulcers. Regardless of the pathophysiologic mechanisms, the characteristic clinical picture is that of an ulcer that fails to re-epithelialize despite the presence of adequate granulation tissue. The wound is usually shallow with irregular margins and pigmented surrounding skin (Barbul, 2005).

Compression therapy is the primary therapy for the management of venous ulcers. The goal of compression therapy is to counteract venous hypertension by facilitating venous return toward the heart. Several different compression devices are available, including compression pumps, elastic and nonelastic bandages, orthotic devices, and compression stockings (Phillips, et al., 2008).

**Diabetic Neuropathic Ulcers:** The major contributors to the formation of diabetic ulcers include neuropathy, foot deformity, and ischemia. It is estimated that 60–70% of diabetic ulcers are due to neuropathy, 15–20% are due to ischemia, and another 15–20% are due to a combination of both. The neuropathy is both sensory and motor and is secondary to persistently elevated glucose levels. Maintaining optimal blood sugar levels is important. The management of diabetic wounds involves local and systemic measures. Treatment options include relief of pressure at the wound site, surgical debridement, control of infection, and arterial reconstruction. It is recommended that treatment should address the possible presence of osteomyelitis, and should employ antibiotics that achieve adequate levels both in the bone and soft tissue. Other therapeutic options include recombinant human growth factors, bioengineered skin substitutes, dressings comprised of extracellular matrix protein, and a variety of synthetic dressings (Barbul, 2005).

### **Negative Pressure Wound Therapy (NPWT) or Vacuum-Assisted Closure (VAC)**

There are various names to describe the treatment of a wound with topical negative pressure including sub-atmospheric pressure therapy or dressing, vacuum sealing technique, VAC, NPWT or dressing, foam suction dressing, vacuum compression, vacuum pack, sealed surface wound suction or sealing aspirative therapy (National Institute for Health and Clinical Excellence [NICE], 2005).

NPWT involves application of a localized vacuum to draw the edges of the wound together and enhance new growth while providing a moist environment conducive to rapid wound healing. Negative pressure is produced in the wound bed by placing a dressing (i.e., open-celled reticulated foam or moistened gauze) in the wound and sealing the dressing to the skin with a transparent adhesive film dressing. A tube embedded in the dressing connects to a vacuum pump to produce subatmospheric pressure and drain off wound exudate. Manufacturers recommend changing the dressing at 48 hours, then two to three times per week as indicated. This technology is primarily intended for chronic wounds that have not healed when treated with other forms of wound care and for minimizing scarring on acute wounds by promoting healing through granulation tissue formation and re-

epithelization .NPWT may be either a primary or secondary line of treatment, depending on the type of wound. The development of negative-pressure techniques for wound healing derives from two theories: removal of wound exudate decreases edema and concentrations of inhibitory factors and increases local blood flow, and negative pressure stretches and deforms the tissue and disturbs the extracellular matrix, which induces biochemical responses that promote wound healing (ECRI, 2008).

### **Complications of Surgically Created Wounds**

NPWT has been proposed as an alternative to surgery to treat complications of surgically created wounds (e.g., sternal wound complication following cardiac surgery). NPWT has been used in patients who have complications of surgically created wounds (e.g., dehiscence) or traumatic wounds (e.g., flap or graft) when there is a need for accelerated formation of granulated tissue that cannot be achieved by traditional topical methods (e.g., the patient has a condition or comorbidity that will not allow for healing times achievable with other topical treatments). In addition, vacuum-assisted wound closure has also been utilized as a noninvasive treatment of deep sternal wound infections following cardiac surgery (i.e., poststernotomy mediastinitis), as an alternative to more invasive treatment such as surgery (e.g., secondary closure or secondary closure with vascularized muscle flaps).

Treatment options in postoperative nonhealing wounds include the following:

- management of infection (e.g., antibiotic therapy)
- wound incision and drainage
- debridement
- rewiring (postcardiac surgery)
- closed irrigation (with antibiotic solution)
- packing of wound
- delayed closure

### **U.S. Food and Drug Administration (FDA)**

The V.A.C.<sup>®</sup> Therapy<sup>™</sup> device (KCI, San Antonio, TX) initially received 510(k) approval from the FDA on March 14, 1995, for promoting wound healing. Under the 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the V.A.C. device prior to marketing it. On December 20, 2002, the V.A.C. received 510(k) clearance to include the indication of partial-thickness burns (FDA, 2002).

On October 10, 2003, the FDA granted 510(k) approval for three additional models of the V.A.C. family of devices, including the V.A.C.<sup>®</sup> ATS<sup>™</sup>, the mini V.A.C.<sup>®</sup>, and the V.A.C.<sup>®</sup> Freedom<sup>™</sup>.

The FDA indications for use states that the V.A.C. family of devices with woundsite feedback control are negative pressure devices used to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. Feedback control is achieved by measuring the level of negative pressure at the wound site (FDA, 2003).

On August 4, 2004, the FDA granted 510(k) approvals for the Versatile 1<sup>™</sup> Wound Vacuum system (BlueSky Medical, Inc., Carlsbad, CA). The device is indicated for patients who would benefit from a suction device (particularly as the device may promote wound healing) or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids, or infectious materials from a patient's airway or respiratory support system either during surgery or at the patient's bedside (FDA, 2004).

The Versatile 1<sup>™</sup> Wound Vacuum system is contraindicated for the following reasons for wound treatment:

- presence of necrotic tissue
- untreated osteomyelitis
- malignancy (except terminal patients for quality of life issues)
- untreated malnutrition
- use on exposed arteries, veins, or organs

## Precautions:

- patients on anticoagulants or difficult hemostasis
- non-compliant patients

## Literature Review

The evidence supporting the use of vacuum-assisted wound therapy in the treatment of chronic nonhealing wounds exists primarily in the form of nonrandomized, controlled trials; prospective and retrospective large and small case series; single center studies; and single case studies.

In a randomized controlled trial, Armstrong et al. (2007) evaluated the proportion and rate of wound healing in acute and chronic wounds after partial foot amputation in individuals with diabetes treated with NPWT delivered by the VAC device or with standard wound therapy (SWT). This study constitutes a secondary analysis of patients enrolled in a 16-week randomized controlled trial of NPWT: 162 open foot amputation wounds (mean wound size 20.7 cm<sup>2</sup>) were included. Acute wounds were defined as the wounds less than 30 days after amputation, whereas chronic wounds as the wounds greater than 30 days. Inclusion criteria consisted of individuals older than 18 years, presence of a diabetic foot amputation wound up to the transmetatarsal level and adequate perfusion. Wound size and healing were confirmed by independent, blinded wound evaluators. There was a significantly higher proportion of acute wounds (SWT=59; NPWT=63) than chronic wounds (SWT=26; NPWT=14), evaluated in this clinical trial (p=0.001). There was no significant difference in the proportion of acute and chronic wounds achieving complete wound closure in either treatment group. Despite this finding, the Kaplan–Meier curves demonstrated statistically significantly faster healing in the NPWT group in both acute (p=0.030) and chronic wounds (p=0.033). Among the patients treated with NPWT via the VAC, there was not a significant difference in healing as a function of chronicity. In both the acute and the chronic wound groups, results for patients treated with NPWT were superior to those for the patients treated with SWT. This study is a secondary analysis of the Armstrong et al. (2005) study that follows.

Armstrong et al. (2005) conducted a multicenter RCT (n=162) to investigate the effect of NPWT compared to standard care in complex wounds secondary to partial foot amputation in patients with diabetes. Patients were randomly assigned to NPWT (n=77), receiving dressing changes every 48 hours. The control group (n=85) received standard moist wound care. Fifty-six percent of the patients healed in the NPWT group compared to 39% of the control group (p=0.040). The rate of wound healing and granulation was faster in the NPWT group (p=0.002). The frequency and severity of adverse events were similar in both groups.

In a randomized, double-masked, controlled trial, Llanos et al. (2006) investigated the effectiveness of negative pressure closure in the integration of split-thickness skin grafts (STSG) to the recipient's site. Sixty patients in a tertiary burn unit having wounds with skin loss which hindered primary closure were included in this study. Patients who were excluded included those with ≥ 20% of total body surface burns, those who were polytraumatized, had surgical contraindications, those who were enlisted in other clinical trials, and those who rejected the informed consent. In all the patients, surgical cleaning of the recipient site and STSG were performed, after which they were randomly assigned between two groups: a group that received a negative pressure closure dressing and were connected to the central aspiration system at -80 mm Hg versus a control group with similar dressing but without connection to negative pressure. All of the wounds were uncovered on the fourth postoperative hospital day. The authors reported that the median loss of the STSG in the negative pressure closure group was 0.0 cm<sup>2</sup> versus 4.5 cm<sup>2</sup> in the control group (p<0.001). The median hospital stay was 13.5 days in the NPC group versus 17 days in the control group (p<0.001). The authors reported that the use of VAC has a positive impact on clinical parameters such as loss of graft and length of hospital stay. The authors suggested negative pressure closure should be routinely used for these kinds of procedures. These findings are similar to the conclusions in another RCT conducted by Moisisidis et al. (2004).

In a randomized prospective study, Stannard et al. (2006) evaluated the use of NPWT to augment healing of surgical incisions and hematomas after high-energy trauma. The patients with draining hematomas were randomized to either a pressure dressing (group A) or a VAC (group B). Additionally, patients with calcaneus, pilon, and high-energy tibial plateau fractures were randomized to either a standard postoperative dressing or a VAC over the sutures. There were 44 patients randomized into the hematoma study. Group A drained a mean of 3.1 days, compared with only 1.6 days for group B (p=0.03). The infection rate for group A was 16%, compared with 8% in group B. An additional 44 patients were randomized into the fracture study. Again, a significant

difference ( $p=0.02$ ) was present when comparing drainage in group A (4.8 days) and group B (1.8 days). No significant difference was present at current enrollment for infection or wound breakdown.

Andrews et al. (2006) retrospectively reviewed the use of the VAC system as a bolster dressing in the management of the radial forearm free flap donor site. Thirty-four patients were included in the study. Exposed tendon did not occur in any of the 14 (0%) patients in which the VAC bolster was used for a minimum of six days. Eleven of the 20 patients (55%) who used the VAC bolster for five days demonstrated small amounts of tendon exposure (< 2 cm) on follow-up clinic examination. The minimum follow-up for all patients was four months. Based on this study, when used for a minimum of six days, the VAC bolster dressing eliminated tendon exposure at the forearm donor site.

Luckraz et al. (2003) conducted a prospective study on the impact of negative pressure wound therapy on healing of sternal wounds. The study consisted of 27 patients with acquired postoperative mediastinal infection who were managed with either VAC as a sole treatment or VAC followed by myocutaneous flap or primary wound closure. Group 1 ( $n=14$ ) received VAC for a median duration of 13.5 days. Group 2 ( $n=13$ ) received VAC for a median duration of eight days, followed by myocutaneous flap ( $n=8$ ) or primary wound closure ( $n=5$ ). The choice of additional treatment was based on wound size (i.e., larger wounds required ultimate surgical closure). The researchers reported that using VAC as the sole treatment produced an overall success rate of 70% healed wounds in patients with infected sternal wounds secondary to cardiac surgery.

Song et al. (2003) retrospectively reviewed, over a two-year period, records of 35 patients with sternal wound complications to evaluate the efficacy of the VAC device as a bridge between debridement and definitive closure. The patients were treated with twice-daily traditional dressing changes or with the wound VAC device. The authors reported that the VAC group displayed a trend toward a shorter interval between debridement and closure (mean of 6.2 days versus 8.5 days for the group receiving traditional dressing changes) and had fewer dressing changes (mean of 3 versus 17, respectively). The researchers concluded that VAC treatment led to faster wound healing and lower usage of resources in the management of patients with sternal wound complications than did traditional treatment.

Joseph et al. (2000) conducted a single-blind RCT to evaluate the efficacy of VAC for chronic wound healing. Patients ( $n=24$ ) with several different wound types were randomized to six weeks of either standard moist dressings or vacuum-assisted wound therapy. A total of 36 wounds were treated. The researchers reported that 64% of the VAC group demonstrated granulation tissue formation, whereas 81% of the wet-to-moist group had inflammation and fibrosis. The researchers concluded that VAC therapy promoted faster healing than standard wet-to-moist dressing and increased the rate of granulation tissue formation.

## Reviews

Ubbink et al. (2008) conducted an updated Cochrane review on topical negative pressure for treating chronic wounds. Two trials were included in the original review. An additional five trials were included in this second update resulting in a total of seven trials involving 205 participants. The seven trials compared topical negative pressure with five different comparator treatments. Four trials compared topical negative pressure with gauze soaked in either 0.9% saline or Ringer's solution. The other three trials compared topical negative pressure with hydrocolloid gel plus gauze, a treatment package comprising papain-urea topical treatment, and cadexomer iodine or hydrocolloid, hydrogels, alginate and foam. These data do not show that topical negative pressure significantly increases the healing rate of chronic wounds compared with comparators. Data on secondary outcomes such as infection rate, quality of life, edema, hospitalization and bacterial load were not reported. The authors concluded that "at present there is little high-level evidence to support the use of TNP in the treatment of chronic wounds. More rigorous evaluation is essential before the use of TNP can become routine and reimbursed for local wound care in clinical and outpatient care settings."

In a systematic review, Gregor et al. (2008) examined the clinical effectiveness and safety of NPWT compared with conventional wound therapy. Seven randomized controlled trials ( $n=324$ ) and 10 non-randomized controlled trials ( $n=278$ ) met the inclusion criteria. Overall, methodologic quality of the trials was poor. Significant differences in favor of NPWT for time to wound closure or incidence of wound closure were shown in two of five randomized controlled trials and two of four non-randomized controlled trials. A meta-analysis of changes in wound size that included four randomized controlled trials and two non-randomized controlled trials favored NPWT. The authors concluded that although there is some indication that NPWT may improve wound healing;

the body of evidence available is insufficient to clearly prove an additional clinical benefit of NPWT. They reported that there were a large number of prematurely terminated and unpublished trials.

In an emerging technology report, ECRI indicates that NPWT is used to promote wound healing in chronic open wounds (e.g., diabetic and pressure ulcers), acute and traumatic wounds (e.g., amputations, burns), subacute wounds (e.g., dehisced wounds), meshed grafts, flaps, and partial thickness burns. The wound should have the basic capacity to heal. ECRI found that the strength of the evidence for NPWT is unacceptably weak at this time, and no evidence-based conclusions on the efficacy of NPWT for wound healing can be reached. The authors reported that better-designed and larger trials are needed to provide data for analysis of NPWT's effectiveness. An update to this 2005 technology report was completed in 2008 which resulted in the same conclusion (ECRI, 2005; 2008).

### Professional Societies/Organizations

The American Society of Plastic Surgeons (ASPS) evidence-based clinical practice guideline for chronic wounds of the lower extremity states, "Although the wound care literature is rife with uncontrolled studies reporting the effectiveness of negative pressure wound therapy, few prospective randomized trials exist. Despite a lack of strong evidence to support its use, negative pressure wound therapy has gained wide acceptance by multiple specialties for a myriad of wounds" (ASPS, 2007).

The American College of Foot and Ankle Surgeons (ACFAS) 2006 diabetic foot disorders clinical practice guideline addresses the treatment of diabetic foot infections. The authors state the primary treatment goal for diabetic foot ulcers is to obtain wound closure as expeditiously as possible. The authors state that along with other dressings, NPWT may be useful to aid in the healing of surgical wounds of the diabetic foot. If the wound fails to show signs of healing, the patient's vascularity, nutritional status, infection control, and wound offloading must be re-evaluated (Frykberg, et al., 2006).

The European Tissue Repair Society (ETRS) presented the following general guidelines for NPWT at the ETRS Open Focus Meeting in November 2000 (ETRS, 2000). The committee advised that the use of NPWT is appropriate for large trauma wounds (e.g., exposed bones, tendons, vessels, and closed joints), large sacral ulcers, poststernotomy disunions (i.e., sternal bone exposed, generally infected, large cavity sometimes exposing the anterior mediastinal area), and postoperative disunions of the abdominal wall. The committee also advised that NPWT should be discontinued under the following conditions:

- A uniform granulation tissue is obtained.
- The patient displays a psychological intolerance to NPWT.
- The wound is infected.
- There is no progression of the aspect and the surface of the wound on two successive dressing changes.

### Summary

There is moderate evidence in the peer-reviewed published literature to indicate that negative pressure wound therapy (NPWT) using a device approved by the U.S. Food and Drug Administration (FDA) is safe and effective for a specific subgroup of patients who have failed a comprehensive, conventional wound therapy program that includes all reasonable, well-established alternative medical treatments. There is also moderate evidence to support the use of this therapy as an alternative to surgery (i.e., secondary closure with or without myocutaneous flap) or in preparation for surgery in patients with poststernotomy mediastinitis. There is insufficient evidence to support the routine use of vacuum-assisted wound therapy.

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## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT <sup>®</sup> Codes	Description
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97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

<b>HCPCS Codes</b>	<b>Description</b>
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes supplies and accessories
E2402	Negative pressure wound therapy electrical pump, stationary or portable

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
250.80-250.83	Diabetes with other specified manifestations
357.2	Polyneuropathy in diabetes
459.81	Unspecified venous (peripheral) insufficiency
707.00-707.09	Decubitus ulcer
707.10-707.19	Ulcer of lower limbs, except decubitus
707.8	Chronic ulcer of other specified sites
707.9	Chronic ulcer of unspecified site
875.1	Open wound of chest (wall), complicated
877.1	Open wound of buttock, complicated
879.1	Open wound of breast, complicated
879.3	Open wound of abdominal wall, anterior, complicated
879.5	Open wound of abdominal wall, lateral, complicated
879.7	Open wound of other and unspecified parts of trunk, complicated
879.9	Open wound(s) (multiple) of unspecified site(s), complicated
890.1	Open wound of hip and thigh, complicated
894.1	Multiple and unspecified open wound of lower limb, complicated
998.31	Disruption of internal operation wound
998.32	Disruption of external operation wound
998.83	Nonhealing surgical wound

**\*Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.**

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	3/15/2008	0064	Negative Pressure Wound Therapy/Vacuum-Assisted Closure (VAC) for Nonhealing Wounds
Great-West Healthcare	1/1/2007	04.251.03	Vacuum-Assisted Wound Closure

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.