



# CIGNA MEDICAL COVERAGE POLICY

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

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

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## Table of Contents

Coverage Policy .....	1
General Background .....	2
Coding/Billing Information .....	7
References .....	8
Policy History.....	11

## Hyperlink to Related Coverage Policies

- Electrical Stimulation for Wound Healing
- Hyperbaric Oxygen Therapy, Systemic & Local
- Pneumatic Compression Devices for Vascular Diseases of the Lower Extremities
- Pressure Reducing Surfaces
- Pulsed Electromagnetic Stimulation
- Tissue-Engineered Skin Substitutes and Platelet-Derived Growth Factors

## INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 customer'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 customer'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 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 ©2011 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.

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## General Background

This information on negative pressure wound therapy/vacuum-assisted closure (VAC) for nonhealing wounds has been developed through consideration of medical necessity and generally accepted standards of medical practice, as well as review of medical literature and government approval status.

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, usually 30 days, 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, 2010).

While there are numerous treatments that have been proposed to treat chronic wounds, some have not been well-studied and therefore their safety and effectiveness are as yet unproven. Proposed approaches include: ultrasound, laser, electromagnetic therapy (EM), electrical stimulation (ES), hyperbaric oxygen, gene therapy,

surgical debridement, surgical revascularization of the affected area, myocutaneous skin flaps or grafting, wet-to-dry dressings, negative pressure wound therapy, vacuum-assisted closure, 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.

### **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, 2009).

### **Chronic Wound Types**

Chronic ulcers of the skin include pressure ulcers, arterial ulcers, venous stasis ulcers, neuropathic diabetic ulcers.

**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. Pressure ulcers generally appear in soft tissue over a bony prominence (Thomas, 2010).

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, 2010).

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, 2010).

### **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 wound is usually shallow with irregular margins and pigmented surrounding skin (Barbul, 2005). Compression is the gold standard of treatment of venous disease. After arterial disease has been excluded, reversal of the effects of venous hypertension through compression bandages and leg elevation is the recommended therapy (Bonilla-Martinez, et al., 2010).

**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).

### **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)**

In November 2009, the FDA issued a Preliminary Public Health Notification: Serious Complications Associated with Negative Pressure Wound Therapy Systems. The FDA issued the alert to make individuals aware of deaths and serious complications, especially bleeding and infection, associated with the use of Negative Pressure Wound Therapy (NPWT) systems, and to provide recommendations to reduce the risk. Although rare, these complications can occur wherever NPWT systems are used, including acute and long-term healthcare facilities and at home. FDA has received reports of six deaths and 77 injuries associated with NPWT systems over the past two years. The FDA recommends selecting patients for NPWT carefully, after reviewing the most recent device labeling and instructions and that the patient is monitored frequently in an appropriate care setting by a trained practitioner. In determining the frequency of monitoring, consider the patient's condition, including the wound status, wound location and co-morbidities. The FDA recommends numerous patient risk factors/characteristics to consider before NPWT use. The FDA recommends that NPWT is contraindicated for these wound types/conditions:

- necrotic tissue with eschar present
- untreated osteomyelitis
- non-enteric and unexplored fistulas
- malignancy in the wound
- exposed vasculature
- exposed nerves
- exposed anastomotic site
- exposed organs

Numerous NPWT systems have received Class II clearance by the FDA including, but may not be limited to, the following:

- The V.A.C.<sup>®</sup> Therapy™ device (KCI, San Antonio, TX)
- Versatile 1™ Wound Vacuum system (BlueSky Medical, Inc., Vista, CA).

### **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. Numerous systematic reviews have noted the lack of quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. Despite a lack of robust evidence to support its use, negative pressure wound therapy (NPWT) has become the standard of care for a 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 (Armstrong, et al., 2007; 2005; Llanos, et al., 2006; Moisidis, et al., 2004; Stannard, et al., 2006; Andrews, et al., 2006; Luckraz, et al., 2003; Song, et al., 2003; Joseph, et al., 2000).

**The Centers for Medicare and Medicaid Services (CMS)/ Agency for Healthcare Research and Quality (AHRQ)/ ECRI Institute Evidence-based Practice Center:** The CMS partnered with the AHRQ and commissioned a review of NPWT devices. AHRQ contracted with the ECRI Institute Evidence-based Practice Center to perform the review (AHRQ, 2009). A technology assessment report on NPWT prepared for the AHRQ found that “the systematic reviews of NPWT reveal several important points about this technology. First, all of the systematic reviews noted the lack of high-quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. The lack of high-quality NPWT evidence resulted in many systematic reviewers relying on low-quality retrospective studies to judge the efficacy of this technology. Second, the other systematic reviews found no studies directly comparing different NPWT devices or components have been published. Direct comparison studies are especially important in determining which dressing approach (foam or gauze) may provide the best potential for wound healing. Third, other systematic reviews concluded that NPWT must be evaluated according to wound type. Wound healing varies according to the type of wound being treated and NPWT benefits described for one wound type cannot be transferred to other wound types. Most wound types have too little high-quality NPWT evidence to judge if NPWT is better than standard care for specific wounds. Studies comparing foam to gauze are needed for each wound type before decisions can be made about which systems or components offer significant therapeutic distinctions.”

**Institute for Clinical Systems Improvement (ICSI):** The 2010 ICSI health care protocol: pressure ulcer treatment and prevention protocol recommends to consider NPWT as an early adjuvant for the treatment of deep, category/stage III and IV pressure ulcers. Of all the adjunct modality studies done on pressure ulcers, electrical stimulation carries the highest level of evidence, followed by NPWT, and then all others. (ICSI, 2010).

### **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 NPWT using a device approved by the U.S. Food and Drug Administration (FDA) is 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.

### Coding/Billing Information

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

#### Covered when medically necessary:

CPT®* Codes	Description
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

HCPCS Codes	Description
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

ICD-9-CM Diagnosis Codes	Description
250.80-250.83	Diabetes with other specified manifestations
357.2	Polyneuropathy in diabetes
459.11	Postphlebotic syndrome with ulcer
459.13	Postphlebotic syndrome with ulcer and inflammation
459.81	Unspecified venous (peripheral) insufficiency
707.00-707.09	Decubitus ulcer
707.10-707.19	Ulcer of lower limbs, except decubitus
707.23	Pressure ulcer stage III
707.24	Pressure ulcer stage IV
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®) ©2010 American Medical Association: Chicago, IL.**

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## References

1. Agency for Health Care Research and Quality (AHRQ). Pressure ulcers in adults: prediction and prevention. Clinical guide. No. 3. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR publication no. 92-0047. 1992 May. Accessed January 30, 2011. Available at URL address: <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.chapter.4409>
2. Agency for Health Care Research and Quality (AHRQ). Treatment of pressure ulcers. Clinical guide. No.15. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR publication no. 95-0652. 1994 Dec. Accessed January 31, 2011. Available at URL address: <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat2.chapter.5124>
3. Agency for Health Care Research and Quality (AHRQ). Negative pressure wound therapy devices. AHRQ technology assessment report. November 12, 2009. Accessed January 31, 2011. Available at URL address: <http://www.ahrq.gov/clinic/ta/negpresswtd/>
4. American Society of Plastic Surgeons (ASPS). Evidence based practice guidelines. Chronic wounds of the lower extremity. May 2007. Accessed January 31, 2011. Available at URL address: [http://www.plasticsurgery.org/Medical\\_Professionals/Health\\_Policy\\_and\\_Advocacy/Health\\_Policy\\_Resources/Evidence-based\\_GuidelinesPractice\\_Parameters.html](http://www.plasticsurgery.org/Medical_Professionals/Health_Policy_and_Advocacy/Health_Policy_Resources/Evidence-based_GuidelinesPractice_Parameters.html)
5. Andrews BT, Smith RB, Chang KE, Scharpf J, Goldstein DP, Funk GF. Management of the radial forearm free flap donor site with the vacuum-assisted closure (VAC) system. *Laryngoscope*. 2006 Oct;116(10):1918-22.
6. Andros G, Armstrong DG, Attinger CE, Boulton AJ, Frykberg RG, Joseph WS, et al.; Tucson Expert Consensus Conference. Consensus statement on negative pressure wound therapy (V.A.C. Therapy) for the management of diabetic foot wounds. *Ostomy Wound Manage*. 2006 Jun;Suppl:1-32.
7. Armstrong DG, Lavery LA, Boulton AJ. Negative pressure wound therapy via vacuum-assisted closure following partial foot amputation: what is the role of wound chronicity? *Int Wound J*. 2007 Mar;4(1):79-86.
8. Armstrong DG, Lavery LA; Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. *Lancet*. 2005 Nov 12;366(9498):1704-10.
9. Attinger CE, Janis JE, Steinberg J, Schwartz J, Al-Attar A, Couch K. Clinical approach to wounds: debridement and wound bed preparation including the use of dressings and wound-healing adjuvants. *Plast Reconstr Surg*. 2006 Jun;117(7 Suppl):72S-109S.

10. Barbul A. Wound healing. In: Brunnicardi C, editor. *Schwartz's Principles of Surgery*. 8<sup>th</sup> ed. Philadelphia, PA: The McGraw-Hill Companies, Inc.; 2005. Ch. 8.
11. Bello YM, Phillips TJ. Recent advances in wound healing. *JAMA*. 2000 Feb 9;283(6):716-8.
12. Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. *Diabetes Care*. 2008 Apr;31(4):631-6. Epub 2007 Dec 27.
13. Bonilla-Martinez ZL, Kirsener RS. Venous ulcers. In: Rakel RE, Bope ET, editors. *Conn's Current Therapy*. 1st ed. Philadelphia, PA: W.B. Saunders; 2010. Section 13.
14. Canadian Coordinating Office for Health Technology Assessment (CCOHTA). Vacuum assisted wound closure therapy. Issue 44. March 2003. Accessed January 31, 2011. Available at URL address: [http://www.cadth.ca/media/pdf/221\\_vac\\_cetap\\_e.pdf](http://www.cadth.ca/media/pdf/221_vac_cetap_e.pdf)
15. Caniano DA, Ruth B, Teich S. Wound management with vacuum-assisted closure: experience in 51 pediatric patients. *J Pediatr Surg*. 2005 Jan;40(1):128-32; discussion 132.
16. CIGNA Government Services. Local Coverage Determination. Negative Pressure Wound Therapy Pumps (L5008). Revision effective date October 1, 2009. Accessed January 31, 2011. Available at URL address: <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>
17. ECRI Institute. Negative Pressure Wound Therapy Devices (AHRQ). Plymouth Meeting (PA): ECRI Institute Health Technology Assessment Information Service; 2009 July. 503 p. Available at URL address: <http://www.ecri.org>
18. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute; 2010 April 16. Negative-pressure Wound Therapy Devices. Available at URL address: <http://www.ecri.org>
19. ECRI Institute. Negative Pressure Wound Therapy for Chronic Wounds. [Emerging Technology evidence report]. Plymouth Meeting (PA): ECRI Institute; 2005 Nov. [updated 2009 June]. Available at URL address: <http://www.ecri.org>
20. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute; 2009 Jul 6. Updated December 15, 2010. Electrical Stimulation and Electromagnetic Therapy for the Treatment of Chronic Wounds. Available at URL address: <http://www.ecri.org>
21. European Tissue Repair Society (ETRS). VAC (vacuum-assisted closure) for the treatment of difficult wounds. ETRS open focus meeting. May 2000. Accessed January 22, 2009. Available at URL address: <http://www.etrso.org/proceedings.html>
22. Evans D, Land L. Topical negative pressure for treating chronic wounds. *Cochrane Database Syst Rev*. In: The Cochrane Library, Issue 4, 2004.
23. Expert Working Group. Vacuum assisted closure: recommendations for use. A consensus document. *Int Wound J*. 2008 Jul;5 Suppl 4:iii-19.
24. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, et al. Diabetic foot disorders a clinical practice guideline (2006 revision). *J Foot Ankle Surg*. 2006 Sep-Oct;45(5 Suppl):S1-S66.
25. Gregor S, Maegele M, Sauerland S, Krahn JF, Peinemann F, Lange S. Negative pressure wound therapy: a vacuum of evidence? *Arch Surg*. 2008 Feb;143(2):189-96.
26. Institute for Clinical Systems Improvement (ICSI). Health Care Protocol: Pressure ulcer treatment and prevention protocol. 2<sup>nd</sup> edition. April 2010. Accessed January 31, 2011. Available at URL address: <http://www.icsi.org/index.aspx>

27. Joseph E, Hamori CA, Bergman S, Roaf E, Swann NF, Anastasi GW. A prospective randomized trial of vacuum-assisted closure versus standard therapy of chronic nonhealing wounds. *Wounds*. 2000;12(3):60-7.
28. Kaufman MW, Pahl DW. Vacuum-assisted closure therapy: wound care and nursing implications. *Dermatol Nurs*. 2003 Aug, 15(4):317-20, 323-6.
29. Lavery LA, Barnes SA, Keith MS, Seaman JW Jr, Armstrong DG. Prediction of healing for postoperative diabetic foot wounds based on early wound area progression. *Diabetes Care*. 2008 Jan;31(1):26-9. Epub 2007 Oct 12.
30. Llanos S, Danilla S, Barraza C, Armijo E, Pineros JL, Quintas M, et al. Effectiveness of negative pressure closure in the integration of split thickness skin grafts: a randomized, double-masked, controlled trial. *Ann Surg*. 2006 Nov;244(5):700-5.
31. Loree S, Dompmartin A, Penven K, Harel D, Leroy D. Is vacuum assisted closure a valid technique for debriding chronic leg ulcers? *J Wound Care*. 2004 Jun;13(6):249-52.
32. Luckraz H, Murphy F, Bryant S, Charman SC, Ritchie AJ. Vacuum-assisted closure as a treatment modality for infections after cardiac surgery. *J Thorac Cardiovasc Surg*. 2003 Feb;125(2):301-5.
33. Moisisdis E, Heath T, Boorer C, Ho K, Deva AK. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. *Plast Reconstr Surg*. 2004 Sep 15;114(4):917-22.
34. National Institute for Health and Clinical Excellence (NICE). Negative pressure wound therapy for the open abdomen. Guidance. December 16, 2009. Accessed January 30, 2011. Available at URL address: <http://www.nice.org.uk>
35. National Institute for Health and Clinical Excellence (NICE). The management of pressure ulcers in primary and secondary care. June 2005. Accessed January 31, 2011. Available at URL address: <http://www.nice.org.uk>
36. National Pressure Ulcer Advisory Panel (NPUAP). Pressure Ulcer Staging. Updated February 2007. Accessed January 31, 2011. Available at URL address: <http://www.npuap.org/>
37. Samson D, Lefevre F, Aronson N. Wound-healing technologies: Low-level laser and vacuum-assisted closure. Evidence Report/Technology Assessment No. 111. Rockville, MD: Agency for Healthcare Research and Quality: December 2004.
38. Song DH, Wu LC, Lohman RF, Gottlieb LJ, Franczyk M. Vacuum assisted closure for the treatment of sternal wounds: the bridge between debridement and definitive closure. *Plast Reconstr Surg*. 2003 Jan; 111(1):92-7.
39. Stannard JP, Robinson JT, Anderson ER, McGwin G Jr, Volgas DA, Alonso JE. Negative pressure wound therapy to treat hematomas and surgical incisions following high-energy trauma. *J Trauma*. 2006 Jun;60(6):1301-6.
40. Stillman RM, Daley BJ, Talavera F, Friedman AL, Zevitz ME, Geibel J. Wound Care. Updated August 19, 2008. Accessed February 3, 2009. Available at URL address: <http://emedicine.medscape.com/article/194018-treatment>
41. Thomas DR. Pressure ulcers. In: Rakel RE, Bope ET, editors. *Conn's Current Therapy*. 1st ed. Philadelphia, PA: W.B. Saunders; 2010. Section 13.
42. Ubbink DT, Westerbos SJ, Evans D, Land L, Vermeulen H. Topical negative pressure for treating chronic wounds. *Cochrane Database Syst Rev*. 2008 Jul 16;(3):CD001898.

43. U. S. Food and Drug Administration (FDA). FDA Preliminary Public Health Notification\*: Serious Complications Associated with Negative Pressure Wound Therapy Systems. 2009 Nov 13. Accessed January 31, 2011. Available at URL address:  
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm190658.htm>
44. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K021500. V.AC.®. 2002 Dec. Accessed January 31, 2011. Available at URL address:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=8138>
45. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K032310. V.AC.®, mini V.A.C.®, V.A.C. Freedom™ 2003 Oct. Accessed January 31, 2011. Available at URL address:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=12514>
46. U.S. Food and Drug Administration (FDA). 510(k) summary. Center for Devices and Radiological Health (CDRH). K042134. Versatile 1 Wound Vacuum System. 2004 Aug. Accessed January 31, 2011. Available at URL address:  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=15925>
47. Wound, Ostomy, and Continence Nurses Society (WOCN). Guideline for prevention and management of pressure ulcers. Mount Laurel (NJ): Wound, Ostomy, and Continence Nurses Society (WOCN); 2010 Jun 1. 96 p. (WOCN clinical practice guideline; no. 2). [341 references]
48. Yang CC, Chang DS, Webb LX. Vacuum-assisted closure for fasciotomy wounds following compartment syndrome of the leg. J Surg Orthop Adv. 2006 Spring;15(1):19-23.

## 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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