Medical Policy

Negative Pressure Wound Therapy in the Outpatient Setting

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<th>Type:</th>
<th>Medical Necessity and Investigational / Experimental</th>
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<tr>
<td>Policy Specific Section:</td>
<td>Durable Medical Equipment</td>
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<tr>
<td>Original Policy Date:</td>
<td>June 13, 2001</td>
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<td>Effective Date:</td>
<td>January 1, 2015</td>
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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Negative pressure wound therapy (NPWT), also known as vacuum-assisted closure (VAC), consists of the use of a negative pressure therapy or suction device which aspirates and removes fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue. The powered (electric) NPWT device may be used 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 in order to create an airtight seal. Negative pressure is applied and the wound effluent is collected in a canister. Although the exact mechanism has not been explained, it is hypothesized negative pressure contributes to wound healing by removing excess interstitial fluid, increasing the vascularity of the wound, and/or creating beneficial mechanical forces that draw the edges of the wound closer together.

A non-powered (mechanical) NPWT system (e.g., SNap® Wound Care System) has also been developed and is currently being investigated.

**Policy**

**Powered (Electric) Negative Pressure Wound Therapy System**

A **powered** negative pressure wound therapy (NPWT) system, when used as part of a comprehensive wound care program which includes controlling factors such as diabetes, nutrition, relief of pressure, etc., may be considered **medically necessary** for any the following indications:

- Chronic (> 90 days) stage III or IV pressure ulcers when **one or both** of the following criteria are met:
  - High-volume drainage interferes with healing
  - Standard dressings cannot be maintained due to anatomic factors
- Traumatic or surgical wounds when **all** of the following criteria are met:
  - Documented failure of immediate or delayed primary closure
  - Exposed bone, cartilage, tendon, or foreign material within the wound
  - **None** of the following contraindications are present:
    - Necrotic tissue with eschar
    - Untreated osteomyelitis
    - Non-enteric and unexplored fistulas
    - Malignancy in the wound
    - Exposed nerves, anastomotic sites, or organs
- Non-healing wounds when **both** of the following criteria are met:
  - Lack of improvement for at least the previous 30 days, despite optimal wound care (e.g., moist topical dressings, debridement of necrotic tissue if present, maintenance of adequate nutritional status)
  - Patient has an underlying clinical condition which is known to negatively impact wound healing including, but not limited to diabetes, malnutrition, small vessel disease, and morbid obesity

**Note:** A **powered** NPWT system initiated by a physician for wound care in the inpatient setting would be allowed in the initial transfer to the outpatient setting to provide continuity of care.
**Powered** NPWT systems for the treatment of other acute or chronic wounds except as noted above are considered **not medically necessary**.

**Continuation of a Powered NPWT System**

Monthly continuation of a **powered** NPWT system, as part of a comprehensive wound care program, may be considered **medically necessary** if the treatment has resulted in documented objective improvements in the wound including **both** of the following:

- The development and presence of healthy granulation tissue
- Progressive wound contracture (shrinkage and spontaneous closure) evidenced by decreasing surface area (length times width) and/or decreasing depth, and/or the commencement of epithelial spread from the wound margins

**Note:** The medical necessity of NPWT beyond four months (including hospital use) will require individual consideration and additional supportive documentation of medical necessity.

Continuation of the powered NPWT system is considered **not medically necessary** when **any** of the following occurs:

- Treatment period has not resulted in documented objective improvement in the wound
- The wound has developed evidence of wound complications contraindicating continued NPWT (See Policy Guideline)
- The wound has healed to an extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments (See Policy Guideline)

**Non-Powered NPWT System**

Use of a **non-powered** NPWT system (e.g., Smart Negative Pressure (SNaP®) Wound Care System) for the treatment of acute or chronic wounds is considered **investigational**.

**Policy Guideline**

There are currently two classifications of NPWT devices:

- Powered or electrically powered devices create a vacuum via an electrically operated pump. The electricity may come from either a wall outlet or battery power.
- Non-powered, mechanical or non-electrically powered pumps create a vacuum through the operation of a mechanical (i.e., spring loaded) device.

The majority of devices used are of the powered or electrically powered type.

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<th>Pressure Ulcer Advisory Panel Staging System</th>
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<td><strong>Stage I</strong></td>
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may extend down to, but not through, underlying fascia

| Stage IV | Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures |

Contraindications of NPWT (United States Food and Drug Administration, 2009; Sullivan et al., 2009):

- Necrotic tissue with eschar present (granulation tissue will not form over inadequately debrided wounds)
- Untreated osteomyelitis (within the vicinity of the wound)
- Non-enteric and unexplored fistulas
- Malignancy within the wound (negative pressure therapy may lead to cellular proliferation)
- Exposed blood vessels, nerves, anastomoses, or organs

Continuation of healing during use of the NPWT system should be monitored at a frequency not less than every 14 days including documentation of wound measurements (e.g., length and width (surface area), or depth).

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

The majority of wounds achieve sufficient closure within six weeks of NPWT; some wounds may require longer. However, use of NPWT is generally not required beyond four months. It is rarely necessary to continue using the device until a wound is completely healed.

**Coding:**

**Powered or Electrically Powered NPWT:**

- **A6550**: Wound care set for negative pressure wound therapy electrical pump, includes all supplies and accessories
- **E2402**: Negative pressure wound therapy electrical pump, stationary or portable

**Application of negative pressure wound therapy using DME systems:**

- **97605**: Negative pressure wound therapy (e.g., negative pressure therapy-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**: total wound(s) surface area greater than 50 square centimeters

**Application of negative pressure wound therapy using disposable, non-DME systems:**

- **97607**: Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and
instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.

- **97608**: Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.

Specific HCPCS codes were developed specific to the NPWT system (such as the Kalypto® system) in which the exudate is collected in the dressing rather than the cannister:

- **K0743**: Suction pump, home model, portable, for use on wounds
- **K0744-K0746**: Code range for absorptive wound dressings to be used with home suction pump coded with K0743

*Non-Powered or Mechanically-powered NPWT:*

Effective 2014, the HCPCS code for a disposable NPWT system was revised to make it applicable to all types of disposable wound suction devices (e.g., Smart Negative Pressure (SNaP®) Wound Care System; PICO® Single Use Negative Pressure Wound Therapy system [Smith&Nephew]):

- **A9272**: Wound suction, disposable, includes dressing and all accessories and components, any type, each

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### Documentation Required for Clinical Review

- History and physical and/or consultation notes including: prior treatment(s)/duration and response, nutritional status, treatment plan and estimated duration of wound VAC therapy
- Initial wound evaluation and description including: type, age and size of wound (length, width, and depth), and amount of drainage
- Operative reports (if applicable)
- Subsequent wound care notes or progress notes including: current treatment, treatment plan, wound measurements, evaluation, progress, and patient compliance

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### APPENDIX to Negative Pressure Wound Therapy in the Outpatient Setting Policy
Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.

For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Powered Negative Pressure Wound Therapy

A powered (electric) negative pressure wound therapy (NPWT) or vacuum assisted closure (VAC) device uses an electric pump to intermittently or continuously apply subatmospheric pressure to the open wound with the goal of creating a controlled, closed wound amenable to surgical closure, grafting, or healing by secondary intention (Hayes Inc., 2007). Negative wound pressure therapy is intended as an adjunct treatment for healing wounds that do not respond to standard treatment. A non-healing wound is one in which all appropriate wound management options have been explored, and there has been no change in the wound for at least two weeks, or the wound exhibits no change in size, an increase in size, absence of granulation tissue, and/or closed non-proliferative wound edges.

Acute and subacute wounds are problematic if they are large in size, especially if bones or tendons are exposed. These wounds are not amenable to primary closure. Acute and subacute wounds may have been the result of traumatic injuries, including burns, gunshot wounds, traumatic amputation, and non-traumatic events such as surgery. In some cases, acute wounds cannot be closed because of infection, exposure of orthopedic hardware, or skin graft failure which may require a repeat surgical procedure. Treatment of acute and subacute wounds
involves complex wound care, including irrigation and aggressive debridement, antibiotics, and definitive closure with skin grafts or muscle flaps (Hayes Inc., 2007).

Chronic wounds have not completed the process of healing in the expected time frame, usually within 30 days, or have proceeded through the healing phase without establishing the expected functional result (Lazarus et al., 1994). These wounds usually do not close without interventions, and are sometimes resistant to healing interventions. Diabetic foot ulcers, pressure ulcers or "bed sores," vascular or venous ulcers, and complications of surgically created sternal wounds commonly become chronic wounds because their etiologies impede healing and persist without proper medical care (Sullivan et al., 2009).

The management and treatment of chronic wounds remains a treatment challenge. Most chronic wounds will heal if the underlying cause, (e.g., venous stasis, pressure, infection, etc.), is addressed. 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. As with any comprehensive wound program, adequate nutritional status, continence control/management, and appropriate pressure reduction measures should always be employed.

Powered negative pressure therapy or suction devices cleared by the United States Food and Drug Administration (FDA) for the purpose of treating chronic wounds include, but are not limited to:

- The V.A.C.® Therapy™ device (Kinetic Concepts Inc. (KCI), San Antonio, TX)
- Versatile 1™ Wound Vacuum system (BlueSky Medical, Inc., Vista, CA)
- RENASYS EZ system and RENASYS GO portable system (Smith & Nephew, Hull, England)

In November 2009 the FDA issued an alert concerning complications (e.g., bleeding and infection) and deaths that had been associated with NPWT systems. An updated alert was issued in February 2011.

In order to reduce the risks associated with NPWT, the FDA recommended the following:

- Increased attention to careful selection of patients for NPWT
- Frequent monitoring in an appropriate care setting by a trained practitioner. In determining the frequency of monitoring, consider the patient's condition, including wound status, wound location and co-morbidities
- Appropriate training prior to prescribing and using NPWT
- Instructions for proper home use of NPWT

Additionally, the FDA stated NPWT was contraindicated for wounds with:

- Necrotic tissue with eschar present
• Untreated osteomyelitis
• Non-enteric and unexplored fistulas
• Malignancy (within the wound)
• Exposed blood vessels, nerves, anastomoses, or organs

The FDA alert also advised “the safety and effectiveness of NPWT systems in newborns, infants and children has not been established at this time and currently, there are no NPWT systems cleared for use in these populations.” However, a number of case reports and very small case series reported experience with infants and small children most commonly for treatment of sternal wounds (Ugaki et al., 2010).

This policy was initially developed based on the 2000 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment that evaluated negative pressure therapy of pressure ulcers, venous ulcers, and diabetic ulcers. The Assessment cited significant methodologic flaws in the literature reviewed at that time. The authors recommended high-quality clinical trials to determine the efficacy of NPWT compared with standard wound management containing the following features:

• Enrollment of a patient population with ulcers refractory to standard treatment after an appropriate period of optimal wound management
• Randomized assignment to treatment group
• Treatment in the control arm that include all of the main components of optimal wound care, e.g., debridement, irrigation, whirlpool treatments, and wet-to-dry dressings
• Outcome measure(s) that represent clinically important end points, such as the percent of patients with complete healing or the percent of patients that required skin grafting

The published peer-reviewed literature including but not limited to randomized and non-randomized controlled trials, prospective uncontrolled studies, retrospective and retrospective controlled analyses, and case studies have evaluated NPWT for numerous types of wounds. Some studies focused on a specific wound type (Ford et al., 2002; Fuchs et al., 2005; Stannard et al., 2006; Psinos et al., 2009) and others focused the type and size of wound, wound chronicity, and duration of symptoms (Braakenburg et al., 2006). The majority of these studies have continued to have small numbers of subjects as well as methodological weaknesses and fail to meet one or more of the criteria suggested by the TEC Assessment (Doss et al., 2002; Ford et al., 2002; Wanner et al., 2003; Eginton et al., 2003; Moues et al., 2004; Braakenburg et al., 2006; Vuerstaek et al., 2006; Armstrong et al., 2007). However, many studies (mainly case series) have reported positive results according to some parameter of wound healing (DeFranzo et al., 2001; Garner et al., 2001; Hersh et al., 2001; Doss et al., 2002; Ford et al., 2002; Moisidis et al., 2004; Moues et al., 2004; O'Conner et al., 2005; Braakenburg et al., 2006; Vuerstaek et al., 2006; Armstrong et al., 2007; Baillot et al., 2009).

Many of the earlier studies used the KCI V.A.C.® device and were indirectly or directly funded by KCI. Treatment protocols varied in duration of treatment (one day to six weeks) and subatmospheric pressure applied to wounds (50 to 150 millimeters mercury (mm Hg)). Additionally, outcomes measured and outcome results varied throughout the studies (these included wound healing, skin graft take rate and graft quality, quality of life, pain, bacterial load of infected wounds and infection rates, mortality and survival rates in poststernotomy...
Numerous systematic evidence reviews have questioned the quality of the evidence supporting the advantages of NPWT compared to other conventional wound treatments including the Cochrane Collaboration (Wasiake & Cleland, 2007; Ubbink et al., 2008). Despite the paucity of robust evidence, NPWT has become a community standard of care for a subgroup of patients who have failed a comprehensive and conventional wound therapy program. The following highlights several systematic reviews of the peer-reviewed literature and Society recommendations regarding the efficacy of NPWT:

The Agency for Healthcare Research and Quality (AHRQ) conducted a systematic review of the evidence on low-level laser therapy or VAC on wound healing outcomes of chronic wounds (Samson et al., 2004). Based on the VAC available published trials, the authors concluded they “did not find a significant advantage for the intervention on the primary endpoint, complete healing, and did not consistently find significant differences on secondary endpoints and may have been insufficiently powered to detect differences.”

Hayes Inc., (2007) evaluated the peer-reviewed literature regarding the safety and efficacy of NPWT to promote wound healing of acute, subacute, and chronic wounds. The review included 25 studies (11 of which were RCTs). The authors advised there was moderate evidence NPWT resulted in improved wound healing in carefully selected patients who had not responded or failed conventional wound therapy, were not appropriate for surgical wound closure, or were at increased-risk for delayed or poor wound healing. Additionally, patient selection criteria had not been clearly defined due to the lack of clinical trials on specific types of wounds. Finally, the evidence was not sufficient to support NPWT usage in patients who responded to conventional wound therapy or who had contraindications to NPWT including active bleeding, anticoagulant use, difficult wound hemostasis, and those cited by the FDA (above). The Hayes Inc., report updated in 2010 and 2011 indicated no modifications on the conclusions cited in 2007.

A Cochrane review of the literature on NPWT for treatment of partial thickness burns found only one RCT (Molnar et al., 2005) that satisfied inclusion criteria, and the methodological quality of the trial was poor (Wasiak & Cleland, 2007). The authors concluded there was a “paucity of high quality RCTs on NPWT for partial thickness burn injury with insufficient sample size and adequate power to detect differences, if there are any, between NPWT and conventional burn wound therapy dressings.”

According to the 2007 American Society of Plastic Surgeons evidence-based clinical practice guideline for chronic wounds of the lower extremity:

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.

In 2008, an update of a 2002 Cochrane review of NPWT for the treatment of chronic wounds was published (Ubbink et al., 2008). A total of seven trials (five RCTs) were reviewed involving 205 participants and compared NPWT with five different treatments (Joseph et al., 2000;
McCallon et al., 2000; Ford et al., 2002; Eginton et al., 2003; Wanner et al., 2003; Moues et al., 2004; Vuerstaek et al., 2006). Four trials compared NPWT with gauze soaked in either 0.9% saline or Ringer's solution. The other three trials compared NPWT with hydrocolloid gel plus gauze, a treatment package comprising papain-urea topical treatment, and cadexomer iodine or hydrocolloid, hydrogels, alginate and foam. The authors reported the data did not show NPWT significantly increased the healing rate of chronic wounds compared with the five different treatments and concluded “trials comparing NPWT with alternative treatments for chronic wounds have methodological flaws and data do demonstrate a beneficial effect of NPWT on wound healing however more, better quality research is needed.”

An AHRQ technology assessment was performed for the Centers for Medicare and Medicaid Services and posted on the AHRQ website (Sullivan et al., 2009). This technology assessment of NPWT devices was analyzing primarily for “therapeutic distinctions” between the various NPWT devices on the market. The Medicare Improvements for Patient and Providers Act of 2008 called for an evaluation of the HCPCS coding decisions for these devices; this assessment was performed to inform that evaluation. The AHRQ assessment, conducted by ECRI Institute, found no studies showing a therapeutic distinction between these devices.

Excerpts from the AHRQ summary are noted below:

We identified a total of 23 other systematic reviews, all published between 2000 and 2008, that covered NPWT devices. These reviews included studies reporting data on NPWT for patients with a broad range of wound types and focused on comparison to other wound treatments (gauze, bolster dressings, wound gels, alginates, and other topical therapies). The systematic reviews of NPWT reveal several important points about the current state of the evidence on 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, no studies directly comparing different NPWT components (such as foam versus gauze dressings) were identified by any of the reviewers.

The authors of this report also commented on a study by Peinemann and colleagues (2008) as follows:

In their systematic review of clinical studies of NPWT, Peinemann sought to identify unpublished completed or discontinued RCTs to gain a broader knowledge of the NPWT evidence. The authors were concerned that previous systematic review conclusions on efficacy and safety based on published data alone may no longer hold after consideration of unpublished data. The authors invited two NPWT device manufacturers (KCI V.A.C.® and BlueSky Medical Group Inc., Versatile 1™ Wound Vacuum System) and authors of conference abstracts to provide information on study status and publication status of sponsored trials. Responses were received from 10 of 17 (59%) authors and both manufacturers. BlueSky Medical Group Inc., however, had not sponsored relevant RCTs and only provided case reports. The authors determined that of 28 RCTs, 13 had been completed, six had been discontinued, six were ongoing, and the status of three could not
be determined. Nine trials were unpublished, and no results were provided by the investigators.

Peinemann et al., (2008) concluded:

Lack of access to unpublished study results data raises doubts about the completeness of the evidence base on NPWT... Furthermore, the practice of study classification and study inclusion varies considerably between reviews. Harmonisation of search strategies and inclusion criteria for studies, as well as adherence to methodological standards, are necessary to decrease variability between systematic reviews.

Gregor and colleagues (2009) included non-randomized trials in their review if there was a concurrent control group. The authors concluded, although there was some indication NPWT may improve wound healing, the evidence was insufficient to clearly prove an additional benefit. They noted the large number of prematurely terminated and unpublished trials of NPWT was a reason for concern. Authors of other systematic reviews, even if they concluded there was evidence of efficacy, called for larger, high quality studies (Gregor et al., 2008; Vikatmaa et al., 2008; Noble-Bell & Forbes, 2008).

Xie and colleagues (2010) identified 17 RCTs of NPWT that met their criteria for systematic review and found consistent evidence of benefit compared with control treatments for diabetic foot ulcers and conflicting evidence for pressure ulcers. In trials involving mixed wounds, evidence was encouraging but the trials were of inadequate quality.

Two recent papers reported identifying groups of patients who may not benefit from NPWT. Schmelzle et al., (2010) reviewed records of 49 patients with open abdominal wounds for more than seven days due to secondary peritonitis who underwent NPWT. Fascial closure could be accomplished in only 11 patients and complications occurred in 43 patients. Re-explorations after starting NPWT were associated with the occurrence of enterocutaneous fistula and were of prognostic value regarding the rate of fascial closure. The authors advised further studies were needed to evaluate whether this subgroup really benefited from NPWT. A retrospective multicenter study of hospitalized patients with spinal cord injuries and stage III/IV pelvic pressure ulcers treated with standard wound care (n = 53) or NPWT (n = 33) measured wound surface over a 28-day observation period (Ho et al., 2010). Over the 28-day period, 59 patients' wounds were classified as healing and 27 as non-healing. The proportion of patients demonstrating a decrease in wound surface area (healing subgroup) was not significantly different between the NPWT and standard care groups. Over the 28-day period, serum albumin concentrations were significantly improved in the healing groups whether or not treated with NPWT. The authors noted “NPWT may have partially contributed to the lower (or to maintaining the lower) serum albumin concentrations in persons who have malnutrition and a reduced ability to compensate for the wound-related protein loss.”

Canadian researchers studied predictors of failure of NPWT closure of sternotomy wounds (Gdalevitch et al., 2010). Twelve risk factors for impaired wound healing were identified before data collection to retrospectively evaluate predictors of NPWT failure. Of 37 patients treated with NPWT between January 1997 and July 2003, eight patients failed NPWT. Of the 12 risk factors, three were found to be predictive of poor outcome: bacteremia, wound depth of four or
more centimeters, and high degree of bony exposure and sternal instability. The authors advised prospective randomized studies were needed to validate these hypotheses.

Runkel and colleagues (2011), an expert panel convened to develop evidence-based recommendations for the use of NPWT, reported the present evidence base is strongest for the use of NPWT on skin grafts and weakest as a primary treatment for burns. An analysis of NPWT for patients with infected sternal wounds concluded, based on six articles and 321 patients, NPWT resulted in a decrease of 7.2 days in hospital length of stay with no significant impact on mortality (Damiani et al., 2011).

In summary, anecdotal and limited clinical trials have demonstrated there is a subset of problematic wounds where the use of NPWT may provide significant clinical benefit. However, due to clinical variability and the limited data, it is not possible to determine prospectively which wounds are most likely to respond favorably to NPWT. Therefore, the policy statement indicates NPWT may be considered medically necessary for acute and chronic wounds with either demonstrated failure to heal despite intense conventional wound therapy for 90 days or more, or for those wounds that have a high probability of failure to heal due to compounding factors involving the wound and the patient. Continued use of NPWT requires objective evidence of wound healing such as the development of healthy granulation tissue and progressive wound contracture.

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

**Non-powered Devices**

The Smart Negative Pressure (SNaP®) Wound Care System (Spiracur, Inc., Sunnyvale, CA) is an ultraportable, non-powered (mechanical) NPWT system designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, subacute wounds and diabetic and pressure ulcers. Available in 2009, the SNaP® device is lightweight (3 ounces), can be worn underneath clothing, and is fully disposable. This system consists of a cartridge, dressing, and strap; the cartridge acts as the negative pressure source. The system is reported to generate negative pressure levels similar to other NPWT systems.

Armstrong and others (2011) reported results of a planned interim analysis of a RCT comparing SNaP® and the KCI Wound V.A.C.® Therapy™ system for the treatment of chronic lower extremity wounds. Patients had venous or diabetic ulcers with surface area between 1 and 100 centimeter squared (cm²) and a diameter less than 10 cm present for more than 30 days despite appropriate care. Dressings were changed per manufacturer direction, two times per week in the SNaP® group and three times per week in the V.A.C.® group. Analysis after 65 patients had enrolled was based on 53 patients who had completed at least four weeks of therapy, (27 SNaP® and 26 V.A.C.®). This analysis found no significant between group differences in the proportion of subjects healed or the percent of wound size reduction (p < 0.05). Survey data indicated dressing changes required less time and use of the SNaP® device interfered less with mobility and activity than the V.A.C.® device. At the start of treatment, wounds in the V.A.C.® group were larger (V.A.C.8.8 + 9.7 cm² versus SNaP4.3 + 4.1 cm²) and had longer duration (13.7 months versus 8.3 months than wounds in the SNaP® group). This study did not provide
comparison with standard treatment protocols. The authors emphasized the wounds treated in this study were predominantly secondary to venous disease and therefore were generally more superficial.

A retrospective study with historical controls compared NPWT using the SNaP® device (n = 28) with wound care protocols that included the use of Apligraf, Regranex, and skin grafting (n = 42) for treatment of lower extremity ulcers (Lerman et al., 2010). Seven patients (25%) in the SNaP® treated group could not tolerate the treatment and were discontinued from the study because of complications (allergic skin reaction (one), wound infection (one), bleeding after debridement preventing reapplication (one), worsening lower extremity edema (one), and the development of maceration severe enough to required discontinuation (n = 3)) and were considered treatment failures. Eighteen of the remaining 21 patients treated with the SNaP® device demonstrated a statistically significant healing trend (p < 0.05). Between-group estimates of time to wound healing by Kaplan-Meier analysis were statistically significantly in favor of the SNaP® treatment group. Multiple modalities were used in treatment of historical controls. The authors acknowledged the large number of dropouts and the limitations of retrospectively controlled studies. They also noted patients in the SNaP® treated group may have benefited from being in an experimental environment particularly because wounds in this group were seen twice per week compared to variable follow-up in the historical controls. This possibly resulted in more frequent debridement in the experimental group.

Other publications have described use of the SNaP® device in case series with small numbers of patients, fewer than 15 patients (Fong et al., 2010; Lerman et al., 2010; Landsman, 2010). Landsman (2010) commented that by removing compliance barriers this device may encourage more frequent use of NPWT for small wounds.

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

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.
This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

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<td></td>
<td>97607</td>
<td>Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.</td>
</tr>
<tr>
<td></td>
<td>97608</td>
<td>Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.</td>
</tr>
<tr>
<td>HCPC</td>
<td>A6550</td>
<td>Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories</td>
</tr>
<tr>
<td></td>
<td>A9272</td>
<td>Wound suction, disposable, includes dressing, all accessories and components, any type, each</td>
</tr>
<tr>
<td></td>
<td>E2402</td>
<td>Negative pressure wound therapy electrical pump, stationary or portable</td>
</tr>
<tr>
<td></td>
<td>K0743</td>
<td>Suction pump, home model, portable, for use on wounds</td>
</tr>
<tr>
<td></td>
<td>K0744</td>
<td>Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches or less</td>
</tr>
</tbody>
</table>
### Types of Negative Pressure Wound Therapy

<table>
<thead>
<tr>
<th>Type</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K0745</td>
<td>Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches</td>
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<tr>
<td>K0746</td>
<td>Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches</td>
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</tbody>
</table>

### ICD9 Details

- **ICD9 Procedure**: None
- **ICD9 Diagnosis**: All Diagnoses
- **Place of Service**: All Places of Service

### Tables

N/A

### Definitions

N/A

### Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Autologous Platelet-Rich Plasma

### Key / Related Searchable Words

- Wound VAC

### References


• Ho CH, Powell HL, Collins JF et al. Poor nutrition is a relative contraindication to negative pressure wound therapy for pressure ulcers: preliminary observations in patients with spinal cord injury. Adv Skin Wound Care 2010; 23(11):508-16.

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/13/2001</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/15/2001</td>
<td>Coverage determination based on external reviews</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>8/1/2006</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>10/15/2007</td>
<td>Policy Review</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>7/1/2011</td>
<td>Policy title change from Vacuum-Assisted Closure (VAC)/Negative Pressure Wound Therapy (NPWT) for Wound Care with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>3/13/2012</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>2/22/2013</td>
<td>Coding update and policy guideline clarification</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>7/03/2014</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
</tbody>
</table>
The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.