Kansas City

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Negative Pressure Wound Therapy in the Outpatient Setting

Policy Number: 1.01.16
Origination: 7/2001
Last Review: 9/2014
Next Review: 9/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for negative pressure therapy when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Initiation of Powered Negative Pressure Wound Therapy (NPWT):

An initial therapeutic trial of not less than 2 weeks using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling factors such diabetes, nutrition, relief of pressure, etc., may be considered **medically necessary** in the following indications:

- Chronic (> 90 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care when there is high-volume drainage that interferes with healing and/or when standard dressings cannot be maintained due to anatomic factors, or
- Traumatic or surgical wounds where there has been a failure of immediate or delayed primary closure AND there is exposed bone, cartilage, tendon, or foreign material within the wound
- Wounds in patients with underlying clinical conditions which are known to negatively impact wound healing which are non-healing (at least 30 days), despite optimal wound care. (Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the negative pressure wound therapy.)

Continuation of Powered NPWT:

Continuation of the powered NPWT system, as part of a comprehensive wound care program, may be considered **medically necessary** following an initial 2-week therapeutic trial if the treatment trial has resulted in documented objective improvements in the wound, and if there is ongoing objective improvement during subsequent treatment. Objective improvements in the wound should include the development and presence of healthy granulation tissue, progressive wound contracture and decreasing depth, and/or the commencement of epithelial spread from the wound margins.

When Policy Topic is not covered

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

- The therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound, OR
- The wound has developed evidence of wound complications contraindicating continued NPWT, OR
- The wound has healed to an extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments.

Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above is considered **not medically necessary**.

Use of non-powered NPWT systems for the treatment of acute or chronic wounds is considered **investigational**.

Considerations

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

In a 2011 update, the FDA noted additional deaths and injury reports with NPWT since 2009. Although rare, these complications can occur wherever NPWT systems are used, including hospitals, long-term care facilities, and at home. Bleeding was the cause of the most serious adverse events, including deaths. The majority of reports of wound infection were related to the retention of dressing pieces in the wounds. FDA recommendations for healthcare providers include the following: select patients for NPWT carefully knowing that NPWT systems are contraindicated for certain wound types, and patient risk factors must be thoroughly considered before use; assure that the patient is monitored frequently in an appropriate care setting by a trained practitioner; be aware of complications associated with dressing changes such as infection and bleeding; be vigilant for potentially life-threatening complications, such as bleeding, and be prepared to take prompt action if they occur. The FDA reported that 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.

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

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

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

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

Description of Procedure or Service

Negative pressure wound therapy (NPWT) consists of the use of a negative pressure or suction device to reduce infection and promote healing in wounds of various etiologies.

Background

The management and treatment of chronic wounds, including decubitus ulcers, remain a treatment challenge. Most chronic wounds will heal only if the underlying cause, i.e., venous stasis, pressure, infection, etc., is addressed. In addition, cleaning the wound to remove nonviable tissue, microorganisms, and foreign bodies is essential to create the optimal conditions for either re-epithelialization (i.e., healing by secondary intention) or preparation for wound closure with skin grafts or flaps (i.e., healing by primary intention). Therefore, debridement, irrigation, whirlpool treatments, and wet-to-dry dressings are common components of chronic wound care.

Negative pressure wound therapy (NPWT) consists of the use of a negative pressure therapy or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue. The devices may be used as an adjunct to surgical therapy or as an alternative to surgery in a debilitated patient. Although the exact mechanism has not been elucidated, it is hypothesized that negative pressure contributes to wound healing by removing excess interstitial

fluid, increasing the vascularity of the wound, reducing edema and/or creating beneficial mechanical forces that lead to cell growth and expansion.

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

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

Regulatory Status
Negative pressure therapy or suction devices cleared by the U.S. Food and Drug Administration (FDA) for the purpose of treating chronic wounds include, but are not limited to: V.A.C.® (Negative pressure therapy Assisted Closure®) Therapy™ (Kinetic Concepts, Inc); Versatile 1™ Wound Negative pressure therapy System (Blue Sky Medical), and RENASYS EZ and RENASYS GO systems (The latter is a portable system) (Smith-Nephew).

A non-powered NPWT device, the SNaP Wound Care System from Spiracur, is a Class II device requiring notification to market but not having FDA premarket approval. It received 510(k) marketing clearance from the FDA in 2009 (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, subacute wounds and diabetic and pressure ulcers.

No NPWT device has been cleared for use in infants and children.

In November 2009, the FDA issued an alert concerning complications and deaths that had been associated with NPWT systems. An updated alert was issued in February 2011. (Available online at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm.)

Rationale

This policy was initially developed from a 2000 TEC Assessment(1) that evaluated negative pressure therapy of pressure ulcers, venous ulcers, and diabetic ulcers. The TEC Assessment concluded that the evidence was insufficient to permit conclusions regarding the effect of the technology on health outcomes and that the efficacy of negative pressure therapy compared to standard wound management should be determined by high-quality clinical trials that contain 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 includes all of the main components of optimal wound care, eg, 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 who require skin grafting.

In 2004, the Blue Cross and Blue Shield Technology Evaluation Center (TEC) prepared a systematic review for the Agency for Healthcare Research and Quality (AHRQ) that concluded that available published trials “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.”(2)

Literature updates for this policy have focused on comparative trials with the features described in the TEC Assessment, eg, enrollment of patients with ulcers refractory to standard treatment, randomization, optimal standard wound care treatment in the control arm, and clinically important end points. The most recent literature search using the MEDLINE database was performed through December 5, 2013. Following is a summary of key literature to date.

Negative pressure wound therapy (NPWT) devices can be classified as either powered, ie, requiring an external power source, or nonpowered, ie, mechanical. The vast majority of evidence is for powered devices and the main discussion of evidence refers to powered devices. The evidence on nonpowered devices will be discussed separately following the review of evidence on powered devices.

Mixed Wound Types

Systematic reviews. A Cochrane review of NPWT for treatment of chronic wounds was published in 2008.(3) A total of 7 trials involving 205 participants were reviewed. The 7 trials compared NPWT with 5 different comparator treatments (gauze soaked in either 0.9% saline or Ringer's solution, hydrocolloid gel plus gauze, a treatment package comprising papain-urea topical treatment, and cadexomer iodine or hydrocolloid, hydrogels, alginate and foam). The authors reported that the data do not show that NPWT significantly increases the healing rate of chronic wounds compared with comparators and concluded that “trials comparing NPWT with alternative treatments for chronic wounds have methodologic flaws and data do demonstrate a beneficial effect of NPWT on wound healing; however, more, better quality research is needed.”

A 2009 AHRQ technology assessment on NPWT devices was performed by ECRI Institute for the Centers for Medicare and Medicaid Services.(4) This technology assessment was looking primarily for “therapeutic distinctions” between the various NPWT devices on the market. The Medicare Improvements for Patient and Providers Act (MIPPA) of 2008 called for an evaluation of the HCPCS coding decisions for these devices, so this assessment was performed to inform that evaluation. The AHRQ assessment found that there were no studies showing a therapeutic distinction between these devices.

Excerpts from the 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 vs. gauze dressings) were identified by any of the reviewers.

The authors of this report also comment on a 2008 study by Peinemann et al(5) as follows:

In their systematic review of clinical studies of NPWT, Peinemann et al. sought to identify unpublished completed or discontinued RCTs [randomized controlled trials] 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 2 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 [randomized controlled trials] and only provided case reports. The authors determined that of 28 [randomized controlled trials], 13 had been completed, 6 had been discontinued, 6 were ongoing, and the status of 3 could not be determined. Nine trials were unpublished, and no results were provided by the investigators. Peinemann et al. concluded that the "lack of access to unpublished study results data raises doubts about the completeness of the evidence base on NPWT.”

In a 2011 publication, Peinemann and Sauerland updated their systematic review of NPWT for the treatment of acute or chronic wounds with a literature search performed in November 2010.(6) They found 9 RCTs in addition to the 12 covered by earlier reviews; 5 of the 9 new trials involved NPWT systems that were not on the market. Only 5 of the 9 new reports assessed the frequency of complete wound closure (Peinemann and Sauerland's primary outcome measure), and a statistically significant effect in favor of NPWT was found in only 2 trials. Due to high potential for bias and because diverse types of wounds were treated, interpretation of results for 8 of the 9 trials was found to be limited. Peinemann and Sauerland concluded that although there may be a positive effect of NPWT, they did not find clear evidence that wounds heal any better or worse with NPWT than with conventional treatment, and good RCTs are still needed.

Gregor et al included nonrandomized trials in their 2008 review if there was a concurrent control group and concluded that though there is some indication that NPWT may improve wound healing, the evidence is insufficient to clearly prove an additional benefit. They note that the large number of prematurely terminated and unpublished trials of the therapy is reason for concern.(7) Authors of other systematic reviews, even if they conclude that there is evidence of efficacy, call for larger, high-quality studies.(8-10)

Randomized controlled studies. Examples of individual RCTs include a 2004 study by Moues et al(11) on the time to readiness for surgical closure among patients with full-thickness wounds of various etiologies. Log-rank test analysis of Kaplan-Meier method time to readiness did not show any statistically significant differences between groups. The median time to readiness for surgical closure was 6 days for negative pressure therapy patients and 7 days for conventionally treated patients ($p=0.19$).

Braakenburg et al compared NPWT using the V.A.C.® system (n=32) with conventional moist wound therapy (n=33) in patients with different types of wounds (operation wounds, diabetic ulcers, pressure sores) that ranged in duration from less than 48-hours-old to longer than 6 weeks.(12) Twenty-six (81%) NPWT patients and 19 (58%) conventional therapy patients reached an end point of wound healing ($p<0.05$). The median healing time was 4 days shorter in the NPWT group (16 days) compared with controls (20 days), a nonsignificant difference. Substantial, unaccounted loss to follow-up (NPWT, 19%; controls, 36%) and ill-defined wound characteristics confound the results.

A publication from 2008 describes an RCT of NPWT carried out in India using a locally constructed device.(13) In this study, 48 patients with diabetic foot ulcers, pressure ulcers, cellulitis/fasciitis, and "other" were randomized to NPWT or moist dressings. One patient in the NPWT group and 12 in the conventionally treated group were lost to follow-up. No statistically significant differences in time to closure were observed between groups, except in a subset analysis of pressure ulcers (mean, 10 [7.11] days for the treatment group and 27 [10.6] days in controls; $p=0.05$]). The high drop-out rate prevents drawing clear conclusions from this study.

Pressure Ulcers

Representative literature includes a small trial that randomized 24 patients with pressure ulcers of the pelvic region to negative pressure therapy or standard wound care.(14) All patients with pelvic pressure sores were eligible for enrollment and were not required to be refractory to standard treatment. There were no significant group differences for the main outcome measure, time to 50% reduction of wound volume (27 [10] days in the negative pressure therapy group and 28 [7] days in the control group). Limitations include the small number of patients in the study, the possibility that the control group may not have received optimal wound management, and a main outcome measure of 50% reduction in wound size, which is not necessarily a clinically important outcome when compared with other potential outcomes such as complete wound healing.

A retrospective multicenter study measured wound surface over a 28-day observation period in hospitalized patients with spinal cord injuries and stage III/IV pelvic pressure ulcers treated with

standard wound care (n=53) or NPWT (n=33).(15) Over the 28-day period, 59 patients' wounds were classified as healing and 27 as nonhealing. The proportion of patients demonstrating a decrease in wound surface area (healing subgroup) was not significantly different between the NPWT and standard care groups.

Diabetic Lower-Extremity Ulcers

A 2013 Cochrane review of NPWT for treating foot wounds in patients with diabetes mellitus included 5 randomized trials with a total of 605 participants. (16) Two of the 5 studies had a total of 502 participants, the remaining 3 were small, with limited reporting, and with an unclear risk of bias. One of the larger studies (described next) was conducted in patients with diabetic foot ulcers, and the second was in patients with postamputation wounds. Both studies showed a benefit of NPWT, but were considered to be at risk of performance bias due to lack of blinding.

The largest study of NPWT for diabetic foot ulcers is a 2008 multicenter randomized controlled comparison of NPWT versus moist wound therapy by Blume et al.(17) Included were 342 patients with Wagner's stage 2 or 3 foot ulcers equal to or greater than 2 cm; the chronicity of the ulcers was not described. Based on intention-to-treat analysis, a greater proportion of NPWT-treated foot ulcers achieved the primary end point of complete ulcer closure (43.2% vs 28.9%) within the 112-day active treatment phase. For the 240 patients (72%) who completed the active treatment phase, 60.8% of NPWT-treated ulcers achieved ulcer closure compared to 40.0% of ulcers treated with moist wound therapy. NPWT patients experienced significantly fewer secondary amputations (4.1% vs 10.2%). Although this study is limited by 28% loss to follow-up, and chronicity of the ulcers was not described, it is of higher quality than the vast majority of literature in this area.

Lower-Extremity Ulcers Due to Venous Insufficiency

Vuerstaek et al compared the efficacy of NPWT using the V.A.C.® system (n=30) with conventional moist wound care (n=30) in patients hospitalized with chronic venous and/or arterial leg ulcers of greater than 6 months' duration.(18) Full-thickness punch skin grafts from the thigh were applied, followed by 4 days of NPWT or conventional care to assure complete graft adherence. Each group then received standard care with nonadhesive dressings and compression therapy until complete healing (primary outcome) occurred. The median time to complete healing was 29 days with NPWT and 45 days in the controls ($p<0.001$). Ninety percent of the ulcers treated with NPWT healed within 43 days, compared with 48% in the control group. These results suggest NPWT significantly hastened wound healing, but the use of skin autografts makes it difficult to discern the contribution of NPWT to the primary outcome.

Burn Wounds

A 2012 Cochrane review identified 1 RCT of NPWT that met the inclusion criteria.(19) The trial had poor reporting with an absence of data and was considered to be at high risk of bias. No conclusions could be drawn at that time regarding the use of NPWT for this indication.

In 2012, Bloemen et al reported a multicenter 4-armed randomized trial with 86 patients that compared a split-skin graft with or without a dermal substitute (Matriderm), with or without NPWT.(20) Outcome measures included graft take at 4 to 7 days after surgery, rate of wound epithelialization, and scar parameters at 3 and 12 months postoperatively. Graft take and wound epithelialization did not differ significantly between the groups. Most measures of scar quality also did not differ significantly between the groups.

Traumatic and Surgical Wounds

A 2012 Cochrane review evaluated the evidence on NPWT for skin grafts and surgical wounds expected to heal by primary intention.(21) Healing by primary intention occurs when the wound edges

are brought together with sutures, staples, tape, or glue, and contrasts with healing by secondary intention, where the wound is left open to heal from the bottom up (eg, for chronic or infected wounds). Five randomized trials with a total of 280 subjects were included in the review. Four of the trials compared NPWT with another type of wound dressing and 1 trial compared different NPWT devices. Outcomes were measured between 4 days and 12 months after surgery. All of the trials were considered to have unclear or high risk of bias, and few studies reported the primary outcome measure for the review (proportion of wounds completely healed). Based on analysis of subsets of the studies, there were no significant differences in the proportion of wounds completely healed, the time to healing, the incidence of seromas, or failed skin grafts. The review concluded that evidence on the effectiveness of NPWT on complete healing of wounds expected to heal by primary intention remains unclear, and that there is a need for high-quality trials with newer NPWT devices.

Randomized Trials. Three RCTs with more than 50 patients, 4 comparative studies with nonconcurrent controls, and numerous case series have been identified in literature searches for this policy. There is an overlap between these literature searches and the Cochrane review for only 1 study.(22) The studies identified describe a variety of wound types treated over periods ranging from several days to several months.

The largest trial on surgical wounds is a 2011 report from an investigator-initiated, industry-sponsored multicenter RCT of inpatient NPWT for closed surgical incisions.(23) (A preliminary report was published in 2006.(24)) Included were 249 blunt trauma patients with 263 high-risk fractures (tibial plateau, pilon, calcaneus) requiring surgical stabilization. The patients were randomized to NPWT applied to the closed surgical incision or to standard postoperative dressings. All patients were maintained as inpatients until wound drainage was minimal, at which time the NPWT was discontinued (mean, 59 hours; range, 21-213). Patients in the NPWT group were ready for discharge in 2.5 days compared with 3.0 days for the control group; this was not significantly different. The NPWT-treated group had significantly fewer infections than the control group (10% vs 19% of fractures, p=0.049). Wound dehiscence after discharge was observed less frequently in the NPWT group than the control group (8.6% vs 16.5%). These results may reflect the efficacy of short-term use of NPWT under highly controlled conditions of inpatient care, but do not address the effectiveness of NPWT in the outpatient setting.

In 2005, Armstrong et al(25) reported an RCT of NPWT using the V.A.C.® system (n=77) and standard moist wound care (n=85) to treat partial foot amputation wounds (average wound duration 1.5 months) in diabetic patients. Forty-three (56%) of NPWT patients achieved complete closure during the 16-week assessment period versus 33 (39%) of controls (p=0.040). Log-rank analysis showed the rate of complete closure was significantly faster with NPWT than in controls. The frequency and severity of adverse events, most commonly infection (32% in both groups), were similar. Intention-to-treat analysis was reported, but substantial unaccounted loss to follow-up (23%), lack of allocation concealment in randomization, and between group differences in wound care limits these results. The authors reported a reanalysis of these data to examine the possible role of wound chronicity on healing in a later paper.(26) This analysis revealed no significant difference in the proportion of acute and chronic wounds that achieved complete wound closure with either therapy, although the Kaplan-Meier method curve demonstrated statistically faster (p=0.03) healing in the NPWT group in both acute and chronic wounds. While these findings suggest that NPWT improves outcomes compared to standard care, this was a post hoc, unplanned reanalysis of data from a study with several flaws and potential biases that limit validity.

Masden et al reported a randomized trial of NPWT for surgical closures at high risk for nonhealing in 81 patients with comorbidities that included diabetes and peripheral vascular disease.(27) At a mean of 113 days follow-up, there was no significant difference in the proportion of patients with wound infection, time to develop infection, or dehiscence between NPWT and dry dressing groups. Overall, 35% of the dry dressing group and 40% of the NPWT group had a wound infection, dehiscence, or both.

Chio and Agrawal published results of a randomized trial of 54 patients comparing NPWT with a static pressure dressing for healing of the radial forearm free flap donor site in 2010.(22) There were no statistically significant differences in wound complications or graft failure (percentage of area for graft failure was 7.2% for negative pressure and 4.5% for standard dressing).

Nonrandomized Controlled Studies. A 2002 trial by Doss et al was a retrospective comparison of negative pressure therapy with conventional wound management for patients with poststernotomy osteomyelitis and featured a nonconcurrent control group.(28) Treatment assignment was at the discretion of the treating surgeon and was mainly dependent on the time period during which the patient was treated. Treatment duration was shorter for the NPWT (17.2 vs 22.9 days), as was length of hospital stay (27.2 vs 33.0 days). A 2011 analysis of NPWT for patients with infected sternal wounds concluded that, based on 6 articles and 321 patients, NPWT resulted in a decrease of 7.2 days in hospital length of stay with no significant impact on mortality.(29)

Yang et al retrospectively reviewed records of 34 patients who underwent NPWT after fasciotomy wounds for traumatic compartment syndrome of the leg and compared them with matched historic controls measuring time to definitive closure (delayed closure with sutures or skin graft).(30) Average time to definitive closure for both lateral and medial wounds was 6.7 days in the NPWT group (68 wounds in 34 patients) and 16.1 days in the controls (70 wounds in 34 patients) ($p<0.05$). In another study of fasciotomy wounds, Zannis et al retrospectively reviewed records of patients with upper- and lower-extremity fasciotomy wounds treated over a 10-year period.(31) Of 142 upper-extremity wounds, 74 received conventional treatment and 68 were treated with NPWT. Of 662 lower-extremity wounds, 196 received only conventional treatment, 370 received only NPWT, and 96 received both treatments. The authors report a higher rate of primary closure using NPWT (82.7%) versus wet-to-dry dressings for all lower-extremity wounds, and 55.6% ($p<0.03$) for upper-extremity wounds. Lack of a contemporaneous control group limits the application of these findings.

Shilt et al compared outcomes for 16 children treated with NPWT after lawnmower injuries to outcomes for 15 historic controls treated with wet-dry or Xeroform dressings.(32) There were no differences in infection rates between groups, and patients treated with NPWT had longer hospital stays. Fifty-three percent of the controls required a free flap versus 19% of the NPWT group. The small number of subjects in this study limits interpretation of the results, as does the lack of a contemporaneous control group.

Observational Studies. Other potential indications for NPWT are reported in case series. These include patients treated with NPWT for deep wound infections following spine surgery,(33,34) surgical site infections in the groin after arterial surgery,(35) and mediastinitis after sternotomy.(36) FDA has not cleared any NPWT devices for use in children; however, a number of case reports and very small case series report experience with infants and small children, most commonly for treatment of sternal wounds.(37)

Canadian researchers studied predictors of failure of NPWT closure of sternotomy wounds.(38) 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, 8 patients failed NPWT. Of the 12 risk factors, 3 were found to be predictive of poor outcome: bacteremia, wound depth of 4 or more cm, and high degree of bony exposure and sternal instability. The authors advise that prospective randomized studies are needed to validate these hypotheses.

Schmelzle et al report a group of patients who may not benefit from NPWT. Schmelzle et al reviewed records of 49 patients with open abdomen for more than 7 days due to secondary peritonitis who underwent NPWT.(39) 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 advise that further studies are needed to evaluate whether this subgroup really benefits from NPWT.

Burns

A 2007 Cochrane review of the literature on NPWT for treatment of partial thickness burns found only 1 RCT that satisfied the inclusion criteria, and the methodologic quality of the trial was poor.(40) The authors concluded that there is a "paucity of high quality [randomized, controlled trials] 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."

In 2011, Petkar et al published an RCT comparing 4 days of NPWT with a locally constructed device versus conventional dressing methods for split-thickness skin grafts.(41) Forty grafts in 30 burn patients were included in the study. The percentage of graft take at 9 days after surgery was assessed by consensus of the treating plastic surgery unit after gross examination and was significantly greater in the NPWT-treated grafts (96.7% vs 87.5%). The mean duration of continued dressing on the grafted area was 8 days for NPWT and 11 days in controls. The duration of therapy was a clinical decision made by the surgeon, taking into account the adherence and stability of the graft.

An expert panel convened to develop evidence-based recommendations for the use of NPWT reported that the evidence base in 2011 was strongest for the use of NPWT on skin grafts and weakest as a primary treatment for burns. (42)

Nonpowered NPWT Devices

One ultraportable, nonpowered (mechanical) gauze-based NPWT device (SNaP Wound Care System) designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, subacute wounds and diabetic and pressure ulcers became available in 2009.

In 2011, Armstrong et al reported results of a planned interim analysis of an RCT comparing SNaP and the KCI Wound VAC Therapy System for the treatment of chronic lower-extremity wounds.(43) The final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.(44) The study randomized 132 patients with lower-extremity venous or diabetic ulcers with surface area between 1 and 100 cm^2 and diameter less than 10 cm and present more than 30 days, despite appropriate care. Dressings were changed per manufacturer direction, 2 times per week in the SNaP group and 3 times per week in the VAC group. Patients were assessed for up to 16 weeks or until complete wound closure; 83 patients (63%) completed the study. Intention-to-treat analysis with the last observation carried forward showed noninferiority in the primary outcome of wound size reduction at 4, 8, 12, and 16 weeks. When adjusted for differences in wound size at baseline, SNaP-treated subjects showed noninferiority to the VAC-treated subjects at 4, 12, and 16 weeks. Kaplan-Meier analysis showed no significant difference in complete wound closure between the 2 groups. At the final follow-up, 65.6% of the VAC group and 63.6% of the SNaP group had wound closure. Survey data indicated that dressing changes required less time, and use of the SNaP device interfered less with mobility and activity than the VAC device. This study is limited by the high loss to follow-up and the lack of comparison with standard treatment protocols.

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.(45) 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 [n=1], wound infection [n=1], bleeding after débridement preventing reapplication [n=1], worsening lower-extremity edema [n=1], and the development of maceration severe enough to require discontinuation [n=3]) and were considered treatment failures. Between-group estimates of time-to-wound healing by Kaplan-Meier analysis favored the SNaP treatment group. This study is limited by the use of historical controls, the multiple modalities used in treatment of controls, and the large number of dropouts. The authors noted that 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.

Other publications have described use of the SNaP device in case series with small numbers of patients, fewer than 15 patients.(46-48) Landsman commented that by removing compliance barriers, this device may encourage more frequent use of NPWT for small wounds.(47)

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2010. The input was near uniform in support of a therapeutic trial of NPWT for chronic pressure ulcers that have failed to heal, for traumatic or surgical wounds that have failed to close when there is exposed bone, cartilage, tendon, or foreign material within the wound, and for nonhealing wounds in patients with underlying clinical conditions known to negatively impact wound healing. The majority of the input agreed that therapeutic trials of NPWT for other acute or chronic wounds would be not medically necessary.

Summary

Negative pressure wound therapy (NPWT) consists of the use of a negative pressure therapy or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue. Evidence from comparative clinical trials demonstrated that there is a subset of problematic wounds for which the use of NPWT may provide a significant clinical benefit. However, due to clinical variability and the limited data, it is not possible to determine prospectively which wounds are most likely to respond favorably to NPWT. Therefore, the policy statement indicates that a therapeutic trial of NPWT of not less than 14 days may be considered medically necessary for chronic wounds that have failed to heal, despite intense conventional wound therapy for at least 90 days, or for those acute and chronic 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 because these wounds are likely to heal with conventional wound management, ie, the evidence does not demonstrate an incremental improvement in wound healing with use of the NPWT for these cases.

Reports with small numbers of patients using the nonpowered (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 larger numbers of patients are needed. Since the impact on net health outcome compared to existing technology is not known, this is considered investigational.

Practice Guidelines and Position Statements

In 2011, an international expert panel on NPWT provided evidence-based recommendations for the use of NPWT in chronic wounds.(49) The expert panel gave a grade C recommendation (based on well-conducted case-control or cohort studies) that NPWT may be used for grade 3 and 4 pressure ulcers until surgical closure is possible/desirable and a grade B recommendation (based on high-quality systematic reviews of case-control or cohort studies) to achieve closure by secondary intention, to reduce wound dimensions, and to improve the quality of the wound bed. For diabetic foot ulcers, the expert panel gave a grade A recommendation (high-quality meta-analyses, systematic reviews of randomized controlled trials [RCTs], or RCTs with a very low risk of bias) that NPWT must be

considered as an advanced wound care therapy and must be considered to achieve healing by secondary intention, and a grade B recommendation that NPWT should be considered in an attempt to prevent amputation or reamputation. Use of NPWT in ischemic lower-limb wounds received a grade C recommendation that NPWT may be considered in specialist hands but never as an alternative for revascularization and a grade D recommendation (based on case series or expert opinion) that the use of NPWT is not indicated in acute limb ischemia. Use of NPWT in venous leg ulcers received a grade B recommendation that as first-line therapy, (compression) is not efficacious; NPWT should be considered to prepare the wound for surgical closure.

Guidelines for the prevention of infections associated with combat-related injuries were endorsed in 2011 by the Infectious Diseases Society of America and the Surgical Infection Society.(50) The guidelines provide a IB recommendation (strong recommendation, moderate-quality evidence) that NPWT should be used in the management of open wounds (excluding central nervous system injuries) to include during aeromedical evacuation of patients.

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) stated in 2009 that current evidence on the safety and efficacy of NPWT for the open abdomen is inadequate in quality and quantity, and clinicians should make special arrangements for audit of the management of all patients with an open abdominal wound.(51)

The 2005 guidance on the management of pressure ulcers in primary and secondary care from the Royal College of Nursing and NICE stated that topical negative pressure treatment was only assessed in one trial with a small sample size and methodologic limitations; while the trial results suggested that topical negative pressure treatment may increase healing rates of pressure ulcers compared with saline gauze dressings; these findings must be viewed with extreme caution. "Practitioners ought to make patients aware of the limited trial-based evidence for the effectiveness of topical negative pressure for pressure ulcer healing and that further research is required to validate the preliminary findings."(52)

The 2007 guidelines from the American Society of Plastic Surgeons (ASPS) states that maintaining a moist environment, while simultaneously removing soluble factors detrimental to wound healing might logically provide optimal conditions for wound healing.(53) Classic dressings include gauze, foam, hydrocolloid, and hydrogels. Fluid-handling mechanisms include absorption, gelling, retention, and vapor transmission. Bioactive dressings include topical antimicrobials, bio-engineered composite skin equivalent, bilaminar dermal regeneration template, and recombinant human growth factor. Finally, NPWT is a mechanical treatment that uses negative pressure to remove wound exudate. Although the wound care literature is rife with uncontrolled studies reporting the effectiveness of NPWT, few prospective randomized trials exist. Despite a lack of strong evidence to support its use, NPWT has gained wide acceptance by multiple specialties for a myriad of wounds.

Included in the American College of Foot and Ankle Surgeons (ACFAS) 2006 guideline on diabetic foot disorders is the following information on NPWT(54): NPWT has become a common adjunctive treatment modality for diabetic foot ulcerations. Use of a vacuum-assisted closure® device (V.A.C.®; KCI, San Antonio, TX) promotes wound healing through the application of topical, subatmospheric, or "negative" pressure to the wound base. This therapy removes edema and chronic exudate, reduces bacterial colonization, enhances formation of new blood vessels, increases cellular proliferation, and improves wound oxygenation as the result of applied mechanical force. These actions are synergistic. Numerous applications of this modality have proven successful, including use over exposed bone, tendons, and hardware to generate granulation tissue. It is also frequently used to facilitate adherence of split-thickness skin grafts, rotational flaps, or tissue substitutes to a wound bed. A recent clinical trial of the V.A.C.® device for the treatment of open amputation wounds in the diabetic foot showed significantly faster healing and development of granulation tissue with NPWT compared with standard moist wound care.

The 2004 guidelines from the Infectious Diseases Society of America (IDSA) do not make a formal recommendation for the use of wound vacuum-drainage systems.(55) However in the section,

“Treatment of Infection, Adjunctive Treatments,” the following is noted: Investigators and industry representatives have advocated many types of wound-care treatments, including wound vacuum-drainage systems, recombinant growth factors, skin substitutes, antimicrobial dressings, and maggot (sterile larvae) therapy. Although each treatment likely has some appropriate indications, for infected wounds, available evidence is insufficient to recommend routine use of any of these modalities for treatment or prophylaxis. These guidelines are in the process of being updated, with publication expected in the winter of 2012.

Medicare National Coverage

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

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

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Billing Coding/Physician Documentation Information

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

A6550 Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories

A7000 Canister, disposable, used with suction pump, each

A7001 Canister, nondisposable, used with suction pump, each

A9272 Mechanical wound suction, disposable, includes dressing, all accessories and components, each

E2402 Negative pressure wound therapy electrical pump, stationary or portable

K0743 Suction pump, home model, portable, for use on wounds

K0744 Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq in or less

K0745 Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 sq in but less than or equal to 48 sq in

K0746 Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq in

G0456 Negative pressure wound therapy, (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area less than or equal to 50 sq cm

G0457 Negative pressure wound therapy, (e.g. vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wounds(s) surface area greater than 50 sq cm

Policy Implementation/Update Information

7/1/01 New policy added to DME section titled *Vacuum Assisted Closure*. Considered medically necessary for:

Patient has a chronic Stage III or Stage IV pressure ulcer, venous or arterial insufficiency ulcer or a chronic ulcer of mixed etiology.

A complete wound therapy program should have been tried or considered and ruled out prior to application of negative pressure wound therapy.

7/1/02 No policy statement changes.

7/1/03 No policy statement changes.

7/1/04 No policy statement changes.

9/1/06 Policy statement revised to indicate this to be investigational. Added to the Medical section. Title changed to *Negative Pressure Therapy for the Treatment of Chronic Wounds*. Final policy updated 2/1/07.

9/1/07 No policy statement changes.

9/1/08 No policy statement changes.

9/1/09 No policy statement changes.

7/1/10 Policy statements revised to indicate three types of wounds (including acute and chronic) were added as medically necessary for a therapeutic trial. All other uses in acute and chronic wounds is not medically necessary.

9/1/10 No policy statement changes.

9/1/11 The term “powered” added to existing policy statements which are unchanged, new policy statement added that non-powered NPWT systems are investigational

1/1/12	Coding updated.
9/1/12	Policy statement for continuation of powered NPWT clarified
9/1/13	Updated coding. No policy statement changes.
9/1/14	No policy statement changes.
