Negative Pressure Wound Therapy in the Outpatient Setting

Policy Number: 1.01.16  Last Review: 9/2016

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**

The application of the negative pressure wound device is considered incidental to the surgical procedure when performed at the same intervention and is not separately payable.

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**

<table>
<thead>
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<th>Populations</th>
<th>Interventions</th>
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<tr>
<td>Individuals: With chronic pressure ulcers</td>
<td>Interventions of interest are: • Negative pressure wound therapy</td>
<td>Comparators of interest are: • Standard wound care</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity</td>
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<tr>
<td>Individuals: With chronic wounds and comorbidities affecting wound healing</td>
<td>Interventions of interest are: • Negative pressure wound therapy</td>
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<td>Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity</td>
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<td>Individuals: With traumatic or surgical wounds (acute or nonhealing)</td>
<td>Interventions of interest are: • Negative pressure wound therapy</td>
<td>Comparators of interest are: • Standard wound care</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity</td>
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<tr>
<td>Individuals: With any wound type (acute or nonhealing)</td>
<td>Interventions of interest are: • Single-use portable negative pressure wound therapy</td>
<td>Comparators of interest are: • Standard negative pressure wound therapy</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity</td>
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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 also be used as an adjunct to surgical therapy or as an alternative to surgery in a debilitated patient.

The evidence for NPWT in individuals who have chronic pressure ulcers includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. All trials are of low quality and at high risk of bias. In addition, most patients were treated in an inpatient setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for NPWT in individuals who have chronic wounds and comorbidities affecting wound healing includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. RCTs have been published on diabetic lower-extremity ulcers of unknown duration, amputation wounds, and nonhealing lower-extremity ulcers due to venous insufficiency. The largest body of evidence is for foot ulcers in patients who have diabetes, showing a higher rate of wound healing and fewer amputations with NPWT. A single RCT in patients with nonhealing leg ulcers who were treated with skin grafts found a faster rate of healing with NPWT. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for NPWT in individuals who have traumatic or surgical wounds (acute or nonhealing) includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are limited data on NPWT as a primary treatment of partial-thickness burns. One RCT found no benefit of NPWT on graft take and wound epithelialization in patients with full-thickness burns. NPWT showed no benefit for the treatment of patients with surgical wounds or skin grafts healing by primary intention, and a systematic review of NPWT for traumatic and surgical wounds found no differences between standard dressing and NPWT in any wound outcome measure. However, 1 small RCT suggests that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. Additional study in a larger sample is needed to evaluate this outcome measure. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for single-use portable NPWT systems in individuals who have any wound type includes an RCT of the nonpowered Smart Negative Pressure (SNaP®) Wound Care System and a pseudorandomized study of the PrevenaTM Incision Management System. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. One study with the SNaP nonpowered Wound Care System showed noninferiority to a V.A.C. device. However, interpretation of this study is limited by a high loss to follow-up and lack of a control group treated with dressings. RCTs with small numbers of patients
using portable electric NPWT systems are insufficient to draw conclusions about its impact on net health outcome, both for the device itself and in comparison with current care. Well-designed comparative studies with larger numbers of patients are needed. Results from larger RCTs are expected. The evidence is insufficient to determine the effects of the technology on health outcomes.

Overall, the 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 limited data, it is not possible to determine prospectively which wounds are most likely to respond favorably to NPWT. In addition, clinical input supports 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. Therefore, 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 wounds of at least 30 days that have a high probability of failure to heal due to compounding factors involving the wound and the patient. For continued use of NPWT beyond 14 days to meet criteria for medical necessity, there must be objective evidence of wound healing, such as the development of healthy granulation tissue and progressive wound contracture.

**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).

Portable systems include the RENASYS™ GO (Smith & Nephew), XLR8 PLUS (Genadyne Biotechnologies), extríCARE® 2400 NPWT System (Devon Medical), the V.A.C. Via™ (KCI) and the PICO™ Single-Use Negative Pressure Wound Therapy System (Smith & Nephew). The Prevena™ Incision Management System (KCI) is designed specifically for closed surgical incisions.

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](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm).)

**Rationale**

This evidence review was initially developed from a 2000 TEC Assessment(1) that evaluated negative pressure therapy of pressure ulcers, venous ulcers, and diabetic ulcers. Literature updates for this review, using the MEDLINE database, have focused on comparative trials with the features described in the 2000 TEC Assessment (eg, enrollment of patients with wounds refractory to standard treatment, randomization, optimal standard wound care treatment in the control arm, and clinically important end points). In addition, literature has been sought on potential benefits of negative pressure wound therapy (NPWT) for healing of acute wounds. The most recent literature update was performed through December 3, 2015.

NPWT devices are classified as either powered (ie, requiring an electrical power source or batteries) or nonpowered (mechanical). Most evidence found in the
literature is for electrically powered devices with large canisters, such as the V.A.C. system, and so the main discussion of evidence refers to this type of device. A number of portable devices have entered the market, and are particularly relevant for use in the outpatient setting. Some portable devices are mechanically powered while others are designed specifically for surgical incisions. Evidence on the newer portable devices is discussed separately following the review of evidence on the larger electrically powered devices.

Mixed Wound Types

Systematic Reviews
Particularly relevant for this evidence review is the effect of NPWT when used in the home setting. In 2014, authors of a systematic review from the Johns Hopkins University Evidence-based Practice Center for Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services reported that due to insufficient evidence, they were unable to draw conclusions about the efficacy or safety of NPWT in the home setting. These authors found that interpretation of the data available was limited by variability in the types of comparator groups, methodological limitations, and poor reporting of outcomes.

Another AHRQ assessment was performed to inform the HCPCS coding decisions for NPWT devices. This 2009 assessment found no studies showing a therapeutic distinction among different NPWT devices.

Evidence on the efficacy of NPWT in an inpatient setting might provide indirect evidence of its efficacy in an outpatient setting. However, a 2004 systematic review from the Blue Cross and Blue Shield Association Technology Evaluation Center that was prepared for AHRQ concluded that available published trials “did not find a significant advantage for the intervention on the primary end point, complete healing, and did not consistently find significant differences on secondary end points and may have been insufficiently powered to detect differences.” Four years later a Cochrane review 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.” More recently, separate Cochrane reviews have been conducted on NPWT for pressure ulcers, diabetic ulcers, venous insufficiency ulcers, burn wounds, skin grafts, and surgical wounds. These systematic reviews have all reached similar conclusions on a lack of high-quality evidence. They are described in greater detail below.

Randomized Controlled Trials
Examples of individual randomized controlled trials (RCTs) include a 2004 study by Moues et al 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 NPWT patients and 7 days for conventionally treated patients (p=0.19).
Braakenburg et al (2006) 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 ulcers) that ranged in duration from less than 48 hours old to longer than 6 weeks.(8) 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 these results.

Mody et al in 2008 reported an RCT of NPWT involving 48 patients, carried out in India using a locally constructed device.(9) In this study, patients with diabetic foot ulcers (n=15), pressure ulcers (n=11), cellulitis/fasciitis (n=11), and “other” (n=11) 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 [SD], 10 [7.11] days for the treatment group vs 27 [10.6] days in controls; p=0.05). The high drop-out rate prevents drawing clear conclusions from this study.

**Pressure Ulcers**

A 2015 Cochrane review included 4 RCTs of NPWT (N=149) for treating pressure ulcers in any care setting, although most of the patients were treated in a hospital setting .(10) Three studies were considered to be at high risk of bias and all evidence was considered to be of very low quality. Only 1 study reported on complete wound healing, which occurred in only 1 of the 12 study participants. The review concluded that there is high uncertainty about the potential benefits and/or harms for this indication.

One representative trial (noted in the 2015 Cochrane review as “awaiting further information from the authors”) randomized 24 patients with pressure ulcers of the pelvic region to NPWT or standard wound care.(11) All patients with pelvic pressure ulcers 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 (mean, 27 days in the NPWT group vs 28 days in the control group). Findings were limited by the small number of patients in the study, the possibility that the control group may not have received optimal wound management, and lack of information on the time to complete wound healing.

**Diabetic Lower-Extremity Ulcers and Amputation Wounds**

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.(12) Two of the 5 trials had a total of 502 participants; the remaining 3 trials 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 was a 2008 multicenter RCT by Blume et al that compared NPWT versus advanced moist wound therapy.(13) Included were 342 patients with Wagner grade 2 or 3 foot ulcers at least 2 cm²; 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 (72%) patients who completed the active treatment phase, 60.8% of NPWT-treated ulcers achieved ulcer closure compared with 40.0% of ulcers treated with advanced moist wound therapy. NPWT patients also experienced significantly fewer secondary amputations (4.1% vs 10.2%, p=0.035). Although 28% of patients in the trial were lost to follow-up and chronicity of the ulcers was not described, this study is still of higher quality than most of the literature in this area.

In 2005, Armstrong and Lavery reported an RCT of NPWT using the V.A.C. system (n=77) compared with standard moist wound care (n=85) to treat nonhealing partial foot amputation wounds (average wound duration: 1.5 months) in patients with diabetes.(14) 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 compared with controls. Frequency and severity of adverse events were similar between groups, with wound infection being the most commonly observed (32% in both groups). A study published in 2010 by Dalla Paola et al also reported that NPWT resulted in more rapid development of granulation tissue, more rapid control of infections, and reduced time to complete closure (65 days vs 98 days) in patients with infected open minor amputations.(15) Interpretation of this study is limited, as the size and chronicity of wounds prior to treatment were not recorded, and the assessments were nonblinded.

Lower-Extremity Ulcers due to Venous Insufficiency
A 2015 Cochrane review identified a single RCT with 60 patients.(16) This study, published by Vuerstaek et al in 2006, was performed in an inpatient setting in conjunction with skin grafts, and 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.(17) 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 in the NPWT group and 45 days in control group (p=0.001). Ninety percent of ulcers treated with NPWT healed within 43 days, compared with 48% in the control group. These results suggest that NPWT significantly hastened wound healing, although the use of skin autografts makes it difficult to discern the contribution of NPWT to the primary outcome. The 2015 Cochrane review did not identify any RCT evidence on the effectiveness of
NPWT as a primary treatment for leg ulcers, nor was there any evidence on the use of NPWT in the home setting.

**Burn Wounds**
A 2014 Cochrane review identified 1 interim report (abstract) of an RCT on NPWT in patients with partial thickness burns.(18) However, there was not enough evidence presented to allow any conclusions to be drawn regarding the efficacy of NPWT on partial-thickness burn wounds.

Not included in the Cochrane review was a 2012 study by Bloemen et al on the effect of NPWT on graft take in full-thickness burn wounds.(19) This was a multicenter 4-armed RCT with 86 patients that compared a split-skin graft with or without a dermal substitute (MatriDerm), with or without NPWT. 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 groups. Most measures of scar quality also did not differ significantly between groups.

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.(20)

**Traumatic and Surgical Wounds**
Identified studies describe various wound types treated over periods ranging from several days to several months. Studies also differ in whether NPWT was used for nonhealing wounds or as a prophylactic treatment for surgical wounds in patients at high risk for nonhealing.

A 2014 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). Nine randomized trials with a total of 785 patients were included in the review. Three trials involved skin grafts, 4 included orthopedic patients, and 2 included general surgery and trauma surgery patients. All of the trials had unclear or high risk of bias. There were no differences between standard dressing and NPWT in surgical site infections, wound dehiscence, reoperation (in incisional wounds), seroma/hematoma, or failed skin grafts. Pain intensity was reported to be lower with “home-made” NPWT compared with commercial devices. Most or all studies appear to have used short-term application of NPWT in an inpatient setting.

A 2015 Cochrane review evaluated the effects of NPWT on the healing of surgical wounds healing by secondary intention in any care setting.(22) Two studies (total N=69 patients) were identified for the review. Although each study reported a reduction in the median time to healing with NPWT, both provided limited outcome data on the number of wounds healed, adverse events, and resource use. The
authors concluded that there is currently no rigorous RCT evidence available regarding the clinical effectiveness of NPWT in the treatment of surgical wounds healing by secondary intention.

The largest trial on prophylactic NPWT for surgical wounds is a 2012 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)) Participants included 249 blunt trauma patients with 263 high-risk fractures (tibial plateau, pilon, calcaneus) requiring surgical stabilization. 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 NPWT was discontinued (mean, 59 hours; range, 21-213 hours). Patients in the NPWT group were ready for discharge in 2.5 days compared with 3.0 days for the control group (a nonsignificant difference). The NPWT 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 in the control group (8.6% vs 16.5%). These results support the efficacy of short-term use of NPWT when used under highly controlled conditions of inpatient care, but provide only indirect evidence of the effectiveness of NPWT in the outpatient setting. A small RCT (N=20) of NPWT in an outpatient setting reported that patients treated with NPWT required significantly fewer dressing changes, reported significantly less pain, and experienced quality-of-life improvements compared to standard wound care.(25) Additional study among a larger sample of patients is needed to evaluate these outcomes.

Other randomized studies report no benefit of NPWT for surgical wounds, as reflected in the conclusions of the 2015 Cochrane review described above. For example, the RCT by Masden et al (2012) examined the use of NPWT for surgical closures at high risk for nonhealing in 81 patients with comorbidities that included diabetes and peripheral vascular disease.(26) 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. Chio and Agrawal (2010) 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.(27) 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). Biter et al (2014) found no significant advantage of 2 weeks of NPWT in a study of 49 patients who underwent surgical excision for pilonidal sinus disease.(28) Complete wound healing was achieved at a median of 84 days in the NPWT group and 93 days in controls.

**Portable Single-Use NPWT Devices**

**SNaP Wound Care System**
The portable, nonpowered (mechanical) gauze-based Smart Negative Pressure (SNaP) Wound Care System became available in 2009. The device is designed to
remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers.

In 2011, Armstrong et al reported results of a planned interim analysis of an RCT comparing the SNaP Wound Care System and the Vacuum Assisted Closure (V.A.C.) Therapy for the treatment of chronic lower-extremity wounds.(29) Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.(30) The study randomized 132 patients with lower-extremity venous or diabetic ulcers present for more than 30 days despite appropriate care having a surface area between 1 and 100 cm² and diameter less than 10 cm. Dressings were changed per the manufacturer’s direction: 2 times per week in the SNaP group and 3 times per week in the V.A.C. 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 V.A.C.-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 V.A.C. 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 V.A.C. device. Subgroup analysis of 40 patients with venous leg ulcers who completed the study showed a significant improvement in the percentage of patients with complete wound closure with SNaP compared to the V.A.C. system (57.9% vs 38.2%, p=0.008).(31) This study is limited by high loss to follow-up and 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.(32) 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 development of maceration severe enough to require discontinuation [n=3]), and so 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 to treat controls, and the large number of dropouts. The authors noted that patients in the SNaPtreated group may have benefited from being in an experimental environment, particularly because wounds in this group were seen twice per week compared with variable follow-up in historical controls.

**PICO Dressing**

PICO is a portable single-use NPWT system that comes with 2 sterile dressings and has a lifespan of 7 days. In 2015, Schwartz et al reported an industry-funded pilot study with 12 patients who had small wounds of various types (13 wounds in total).(33) A key inclusion criterion was complete failure to progress over the
previous 4 weeks. During the 4 weeks of PICO application, wound size decreased and wound appearance improved. There was no control group in this pilot study and no wound closures during the short follow-up period. The authors noted that in unpublished data, the device was not effective on skin graft donor sites. Additional study is needed.

Prevena System
Prevena is a single-use NPWT system designed specifically for incisions. In 2013, Grauhan et al reported a pseudorandomized trial (alternating assignment) with 150 consecutive obese patients who underwent cardiac surgery via a median sternotomy.(34) Use of the Prevena system for 6 to 7 days beginning immediately after suturing led to a reduction in rates of wound infection compared with standard wound care (4% vs 16%, p=0.027). Gram-positive skin flora were found in 1 patient in the Prevena group and 10 patients in the wound care group. This positive study was performed in an inpatient setting. A randomized trial involving a larger number of patients with sternal midline incisions is scheduled to be completed in 2016.

In 2014, Pauser et al reported a small RCT (N=21) of Prevena in patients who had undergone hemiarthroplasty for femoral neck fractures.(35) Use of the Prevena system resulted in a significant reduction of seroma size, days of wound secretion, wound care time, and need for dressing changes. Larger RCTs are needed to assess these outcomes.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<td>Negative Pressure Wound Therapy. Therapy Effects and the Impact on the Patient’s Quality of Life</td>
<td>200</td>
<td>Jan 2016</td>
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<td>NCT02195310a</td>
<td>The Use of PrevenaTM Incision Management System on Clean Closed Sternal Midline Incisions in Subjects at High Risk for Surgical Site Occurrences</td>
<td>504</td>
<td>Feb 2016</td>
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<tr>
<td>NCT02127281a</td>
<td>Randomized Controlled Trial of Wound Management With Negative Pressure Dressing Versus Standard Dressing After Knee and Hip Revision Arthroplasty</td>
<td>160</td>
<td>Mar 2016</td>
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<tr>
<td>NCT02395159</td>
<td>Reduction of Groin Wound Infections After Vascular Surgery in Patients With Risk Factors by the Use a Negative Pressure Wound Incision Management System (KCI Prevena)</td>
<td>204</td>
<td>Mar 2016</td>
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<tr>
<td>NCT02064270a</td>
<td>A Prospective, Randomized, Controlled Clinical Study to Assess the Prevention of Postsurgical Incision Healing Complications in Patients Undergoing Primary or Revision Total Knee Arthroplasty (TKA) or Total Hip Arthroplasty (THA), Treated With Either Single-Use Negative Pressure Wound Therapy (NPWT) or Standard Postsurgical</td>
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<td>NCT</td>
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<td>NCT02289157</td>
<td>Negative Pressure Wound Therapy in High Risk Patients Undergoing Cesarean</td>
<td>440</td>
<td>Jan 2017</td>
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<tr>
<td>NCT2509260</td>
<td>A Randomized Controlled Trial of Prevena™ Incisional Negative Pressure Wound Therapy to Reduce Surgical Site Infection in Reoperative Colorectal Surgery</td>
<td>298</td>
<td>Jul 2017</td>
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<tr>
<td>NCT02007018</td>
<td>Negative Pressure Wound Therapy Use to Decrease Surgical Nosocomial Events in Colorectal Resections (NEPTUNE)</td>
<td>300</td>
<td>Sep 2017</td>
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<tr>
<td>NCT02461433</td>
<td>The SAVIOR Trial: Surgical Application of Vac Dressings In Obese Patients to Reduce Wound Complications</td>
<td>108</td>
<td>Sep 2017</td>
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<td>NCT01913132</td>
<td>PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - a Prospective Randomized Trial</td>
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<td>NCT02309944a</td>
<td>Negative Pressure Wound Therapy in Obese Gynecologic Oncology Patients: A Randomized Controlled Trial</td>
<td>200</td>
<td>Dec 2017</td>
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<tr>
<td>NCT02348034</td>
<td>A Randomized Controlled Trial Exploring the Ability of Negative Pressure Wound Therapy (NPWT) to Reduce Colorectal Surgical Site Infections (SSI)</td>
<td>398</td>
<td>Dec 2017</td>
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<tr>
<td>NCT02467998</td>
<td>The Registry of Negative Pressure Wound Therapy for Chronic Wounds and Ulcers</td>
<td>50,000</td>
<td>Jan 2020</td>
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<tr>
<td>NCT01821664</td>
<td>Vascular Graft Infections - Epidemiology, Best Treatment Options, Imaging Modalities and Impact of Negative Pressure Wound Therapy</td>
<td>1800</td>
<td>Mar 2023</td>
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<tr>
<td>Unpublished</td>
<td>Use of Incisional Negative Pressure Wound Therapy for Prevention of Postoperative Infections Following Caesarean Section in Women With BMI &gt;=30</td>
<td>948</td>
<td>Apr 2015</td>
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<tr>
<td>NCT02020018a</td>
<td>Negative Pressure Wound Therapy for Prevention of Wound Infection After Heart Surgery</td>
<td>950</td>
<td>Jun 2015</td>
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Summary of Evidence

The evidence for negative pressure wound therapy (NPWT) in individuals who have chronic pressure ulcers includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. All trials are of low quality and at high risk of bias. In addition, most patients were treated in an inpatient setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for NPWT in individuals who have chronic wounds and comorbidities affecting wound healing includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. RCTs have been published on diabetic lower-
extremity ulcers of unknown duration, amputation wounds, and nonhealing lower-extremity ulcers due to venous insufficiency. The largest body of evidence is for foot ulcers in patients who have diabetes, showing a higher rate of wound healing and fewer amputations with NPWT. A single RCT in patients with nonhealing leg ulcers who were treated with skin grafts found a faster rate of healing with NPWT. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for NPWT in individuals who have traumatic or surgical wounds (acute or nonhealing) includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are limited data on NPWT as a primary treatment of partial-thickness burns. One RCT found no benefit of NPWT on graft take and wound epithelialization in patients with full-thickness burns. NPWT showed no benefit for the treatment of patients with surgical wounds or skin grafts healing by primary intention, and a systematic review of NPWT for traumatic and surgical wounds found no differences between standard dressing and NPWT in any wound outcome measure. However, 1 small RCT suggests that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. Additional study in a larger sample is needed to evaluate this outcome measure. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for single-use portable NPWT systems in individuals who have any wound type includes an RCT of the nonpowered Smart Negative Pressure (SNaP®) Wound Care System and a pseudorandomized study of the PrevenaTM Incision Management System. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. One study with the SNaP nonpowered Wound Care System showed noninferiority to a V.A.C. device. However, interpretation of this study is limited by a high loss to follow-up and lack of a control group treated with dressings. RCTs with small numbers of patients using portable electric NPWT systems are insufficient to draw conclusions about its impact on net health outcome, both for the device itself and in comparison with current care. Well-designed comparative studies with larger numbers of patients are needed. Results from larger RCTs are expected. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Clinical Input Received From 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.
2010 Input
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. Most of the input agreed that therapeutic trials of NPWT for other acute or chronic wounds would be not be medically necessary.

Practice Guidelines and Position Statements

International Expert Panel on Negative Pressure Wound Therapy
In 2011, an international expert panel on NPWT provided evidence-based recommendations for the use of NPWT in chronic wounds.(36) 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 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.

Infectious Diseases Society of America and Surgical Infection Society
Guidelines for the prevention of infections associated with combat-related injuries were endorsed in 2011 by the Infectious Diseases Society of America (IDSA) and the Surgical Infection Society.(37) 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), including during aeromedical evacuation of patients.

The 2012 guidelines from IDSA for the diagnosis and treatment of diabetic foot infections state that no adjunctive therapy has been proven to improve resolution of infection, but for selected diabetic foot wounds that are slow to heal, clinicians might consider using NPWT (weak recommendation, low quality evidence).(38)
National Institute for Health and Clinical Excellence
The U.K.’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. (39)

A 2015 NICE Clinical Guideline on diabetic foot problems recommends consideration of NPWT after surgical débridement for diabetic foot ulcers on the advice of the multidisciplinary foot care service. (40) It was noted that the evidence reviewed for NPWT was limited and of low quality, and that it would be useful to have more evidence for this commonly used treatment.

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 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.” (41)

American Society of Plastic Surgeons
The 2007 guidelines from the American Society of Plastic Surgeons states that maintaining a moist environment, while simultaneously removing soluble factors detrimental to wound healing, might logically provide optimal conditions for wound healing. (42) Classic dressings include gauze, foam, hydrocolloid, and hydrogels. Fluid-handling mechanisms include absorption, gelling, retention, and vapor transmission. Bioactive dressings include topical antimicrobials, bioengineered 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.

American College of Foot and Ankle Surgeons
Included in the 2006 guideline on diabetic foot disorders from the American College of Foot and Ankle Surgeons is the following information on NPWT(43): 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.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**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 NPWT 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.

References:
29. Armstrong DG, Marston WA, Reyzelman AM, et al. Comparison of negative pressure wound therapy with an ultraportable mechanically powered device vs. traditional electrically powered


97605 Negative pressure wound therapy (e.g., negative pressure therapy-assisted drainage collection), utilizing durable medical equipment (DME), 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), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

97607  Negative pressure wound therapy, (eg, 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, (eg, 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

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 (code deleted 12/31/14)

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 (code deleted 12/31/14)

**ICD-10 Codes**

L89.000-  Pressure ulcer code range, specified site, code range includes options
for all body areas as well as designation of stages

Pressure ulcer code range, unspecified site, code range includes options for stage of ulcer

- Open wound of head and face, code range, 7th digit extender includes stage of healing
- Open wound of neck, code range, 7th digit extender includes stage of healing
- Open wound of thorax, code range, 7th digit extender includes stage of healing
- Open wound of abdomen, lower back, pelvis and external genitals, code range, 7th digit extender includes stage of healing
- Open wound of shoulder and upper arm, code range, 7th digit extender includes stage of healing
- Open wound of elbow and forearm, code range, 7th digit extender includes stage of healing
- Open wound of wrist, hand and fingers, code range, 7th digit extender includes stage of healing
- Open wound of hip and thigh, code range, 7th digit extender includes stage of healing
- Open wound of knee and lower leg, code range, 7th digit extender includes stage of healing
- Open wound of ankle, foot and toes, code range, 7th digit extender includes stage of healing

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.
9/1/15 No policy statement changes. Codes updated to reflect revised and deleted codes.
9/1/16 No policy statement changes.

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