

Medical Policy



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Title: Vacuum Assisted Wound Closure (VAC)

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With diabetic lower-extremity ulcers or amputation wounds 	Interventions of interest are: <ul style="list-style-type: none"> Outpatient negative pressure wound therapy 	Comparators of interest are: <ul style="list-style-type: none"> Standard wound care 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Change in disease status Morbid events Quality of life Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic pressure ulcers	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With lower-extremity ulcers due to venous insufficiency	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Compression therapy	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With burn wounds	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With traumatic or surgical wounds	Interventions of interest are: • Outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
Individuals: • With any wound type (acute or nonhealing)	Interventions of interest are: • Portable single-use outpatient negative pressure wound therapy	Comparators of interest are: • Standard negative pressure wound therapy	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity

DESCRIPTION

Negative pressure wound therapy (NPWT) involves use of a negative pressure or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue and wound healing.

OBJECTIVE

The objectives of this policy are to evaluate whether negative pressure wound therapy improves outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds; and to assess the evidence on the use of portable NPWT devices.

BACKGROUND

Chronic Wounds

Management

The management and treatment of chronic wounds, including decubitus ulcers, is challenging. Most chronic wounds will heal only if the underlying cause, ie, venous stasis, pressure, infection, is addressed. Also, cleaning the wound to remove non-viable tissue, microorganisms, and foreign bodies is essential to create the optimal conditions for either re-epithelialization (ie, healing by secondary intention) or preparation for wound closure with skin grafts or flaps (ie, healing by primary intention). Therefore, débridement, 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 also 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 nonpowered (mechanical) NPWT system has also been developed; 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 evidence review is use of NPWT in the outpatient setting. It is recognized that patients may begin using the device in the inpatient setting as they transition to 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: Vacuum Assisted Closure® Therapy (V.A.C., also known as negative pressure wound therapy; Kinetix Concepts Inc.); Versatile 1™ (V1) Wound Vacuum System (Blue Sky Medical), RENASYS™ EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical Electronics), and PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew).

Portable systems include the RENASYS™ GO (Smith & Nephew), XLR8 PLUS (Genadyne Biotechnologies), extriCARE® 2400 NPWT System (Devon Medical Inc.), 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 nonpowered 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 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, FDA issued an alert concerning complications and deaths associated with NPWT systems. An updated alert was issued in February 2011.¹

FDA product code: OMP.

POLICY

Predetermination is strongly encouraged:

- A. Vacuum Assisted Wound Closure (VAC) is considered **medically necessary** in the home setting to promote the closure of chronic wounds when initiated in the home setting, or in the hospital or skilled nursing facility prior to discharge, when **ONE** of the following chronic wound conditions is present:
- Pressure ulcers – Stage III or Stage IV, **OR**
 - Venous or arterial insufficiency ulcers, **OR**
 - Dehisced wounds or wounds with exposed hardware or bone, **OR**
 - Neuropathic ulcers, **OR**
 - Complications of a surgically created (ie, large incisional hernia with mesh) or traumatic wound or diabetic lower extremity ulcer where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment, **OR**
 - Post sternotomy wound infection or mediastinitis

AND ALL OF THE FOLLOWING

- It is used as an adjunct therapy or as an alternative to surgery; **AND**
- There is support to change the device and provide home care for the wound; **AND**
- Patient selection criteria have been met (see Policy Guidelines, below)

NOTE: For VAC to be initiated in the home setting, progressive wound healing has failed following 30 days of conservative wound treatment. (Treatment less than 30 days can be reviewed by a consultant if medical records are provided).

- B. VAC therapy post skin grafting will be considered **medically necessary** for up to 2 weeks. Continuation beyond will be reviewed on a case by case basis.
- C. Post breast reduction surgery, VAC is considered **medically necessary** if the patient's BMI is 40 or more. Approval length: 1 week.
- D. Non-electric vacuum assisted wound therapy (eg, SNaP™ Wound Care Device) is considered **experimental / investigational** for all conditions.
- E. Portable, battery-powered, single-use (disposable) vacuum assisted wound therapy devices (eg, the PICO™ Single Use Negative Pressure Wound Therapy System or the V.A.C. Via™ Negative Pressure Wound Therapy System) are considered **experimental / investigational** for all conditions.
- F. Post surgical VAC placement on new or acute wounds will be reviewed on a case by case basis.
- G. All other applications for VAC therapy are considered **not medically necessary**.

Policy Guidelines

1. Patient Selection Criteria

The criteria listed below, as items a. through f. must be met for all conditions:

- a. The wound has been débrided and is free of all the following:
 - Nonviable or necrotic tissue (eschar)
 - Macroscopic contamination
 - Non-enteric and unexplored fistulae
 - Malignant or metastatic cells
 - Active bleeding
 - Pressure on wound
- b. The wound does NOT contain exposed arteries or veins
- c. The patient is free from active osteomyelitis
- d. The wound depth is at least 1 mm or greater. Wounds with a depth of <1 mm cannot accommodate the sponge / foam.
- e. The medical record documents that the patient is NOT nutritionally compromised, or if nutritionally compromised, the medical record documents appropriate interventions have been implemented.
- f. The medical record documents that the patient is willing and able to comply with using continuous or intermittent VAC application 22 of 24 hours per day.
- g. The additional criteria listed below must be met for specific wound types and treatment regimes:
 - 1) Neuropathic ulcers:
The patient has been on a comprehensive management program and evidence of adequate vascularization and appropriate treatment to relieve pressure on a foot ulcer has been rendered.

- 2) Venous or arterial insufficiency ulcers:
The patient has had compressive bandages and/or garment and leg elevation consistently applied and/or utilized under physician supervision and ambulation has been encouraged.
- h. VAC approved may be allowed up to 4 weeks before re-review.

Continuation of Treatment

1. For coverage to continue beyond initial approval period, the medical records (progress notes) should indicate the following:
 - a. Weekly assessment of the dimensions and characteristics of the wound(s) by a licensed health care professional
 - b. Documentation of progressive wound healing without intervening complications at least monthly.
 - c. Discontinue VAC if wound shows no progress for 2 weeks.
 - d. Maximum duration of VAC approval, without consultant review, is 4 months.

RATIONALE

This policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through November 15, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function^{3/4}including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

This review was informed by a 2000 TEC Assessment that evaluated negative pressure therapy of pressure ulcers, venous ulcers, and diabetic ulcers.² Literature updates for this review 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 endpoints). Also,

literature has been sought on the potential benefits of negative pressure wound therapy (NPWT) for the healing of acute wounds.

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 (eg, the VacuumAssisted Closure Therapy device [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 designed specifically for surgical incisions. Evidence on the newer portable devices is discussed following the review of evidence on the larger electrically powered devices.

The primary endpoints of interest for trials of wound closure are as follows, consistent with guidance from the U.S. Food and Drug Administration for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:

1. Incidence of complete wound closure
2. Time to complete wound closure (reflecting accelerated wound closure)
3. Incidence of complete wound closure following surgical wound closure
4. Pain control.

Mixed Wound Types

Systematic Reviews

The authors of a systematic review for the Agency for Healthcare Research and Quality and the Centers for Medicare & Medicaid Services (2014) reported that due to insufficient evidence, they were unable to draw conclusions about the efficacy or safety of NPWT in the home setting.³ There were three retrospective cohort studies on diabetic foot ulcers and arterial ulcers, an RCT and two retrospective cohort studies on pressure ulcers, and a retrospective cohort on venous ulcers. Six studies used the V.A.C., and the other used the Smart Negative Pressure (SNaP) Wound Care System device. Reviewers found that interpretation of available data was limited by variability in the types of comparator groups, methodologic limitations, and poor reporting of outcomes.⁴

Another Agency for Healthcare Research and Quality assessment was performed to inform the HCPCS coding decisions for NPWT devices. This 2009 assessment found no studies showing a therapeutic distinction between different NPWT devices.⁵

Diabetic Lower-Extremity Ulcers and Amputation Wounds

Clinical Context and Test Purpose

The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with diabetic lower-extremity ulcers or amputation wounds.

The question addressed in this evidence review is: does NPWT improve outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds; and to assess the evidence on the use of portable NPWT devices?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with diabetic lower-extremity ulcers or amputation wounds.

Interventions

The therapy being considered is outpatient NPWT.

Comparators

Comparators of interest include standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

Timing

Though not completely standardized, follow-up for diabetic lower-extremity ulcers or amputation wounds symptoms would typically occur in the months to years after starting treatment.

Setting

Patients with diabetic lower-extremity ulcers or amputation wounds are actively managed by endocrinologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

A 2013 Cochrane review of NPWT for treating foot wounds in patients with diabetes included 5 randomized trials (total n=605 participants).⁶ 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 (Blume et al [2008]⁷, described next) was conducted in patients with diabetic foot ulcers, and the second in patients with postamputation wounds. There were statistically significant improvements in the proportion of wounds healed and the time to healing. For the proportion of wounds that healed, the relative risk was 1.44 (95% confidence interval [CI], 1.03 to 2.01) and, for the time to ulcer healing, the relative risk was 1.85 (95% CI, 1.40 to 2.45). The data also suggested that NPWT reduced the risk of amputation compared with moist wound therapy. Reviewers concluded that there was some evidence to suggest that NPWT was more effective than standard care, but the findings were uncertain due to the risk of bias in the unblinded studies. Reviewers recommended further study to reduce uncertainty around decision making.

The largest study of NPWT for diabetic foot ulcers was a multicenter industry-sponsored RCT by Blume et al (2008) that compared NPWT with advanced moist wound therapy.⁷ Included were 342 patients with Wagner grade 2 or grade 3, foot ulcers of 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 endpoint of complete ulcer closure (43.2% vs 28.9%, p=0.007) within the 112-day active treatment phase. For the 240 (72%) patients who completed the active treatment phase, 60.8% of NPWT-treated ulcers closed 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).

Borys et al (2018) conducted a prospective observational study to assess the short-term efficacy, safety, and long-term outcomes of NPWT in treating diabetic foot ulcers. Researchers assigned 75 patients to NPWT (n=53) or standard care (n=22) based on wound size. Analysis after one-year follow-up showed similar results for both groups, leading researchers to conclude NPWT is a safe alternative to but not necessarily more efficacious than the current standard of care. Limitations include small sample size, the observational design, and nonconsideration of risk factors other than wound size.⁸

Section Summary: Diabetic Lower-Extremity Ulcers and Amputation Wounds

The evidence on NPWT for diabetic lower-extremity ulcers and amputation wounds includes RCTs and a systematic review of RCTs. Although there is some uncertainty due to the risk of bias in the unblinded studies, there were higher rates of wound healing and fewer amputations with NPWT, supporting its use for diabetic lower-extremity ulcers and amputation wounds.

Chronic Pressure Ulcers

Clinical Context and Test Purpose

The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with chronic pressure ulcers.

The question addressed in this evidence review is: does NPWT improve outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds; and to assess the evidence on the use of portable NPWT devices?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with chronic pressure ulcers.

Interventions

The therapy being considered is outpatient NPWT.

Comparators

Comparators of interest include standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

Timing

Though not completely standardized, follow-up for chronic pressure ulcers symptoms would typically occur in the months to years after starting treatment.

Setting

Patients with chronic pressure ulcers are actively managed by dermatologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

A 2015 Cochrane review included 4 RCTs of NPWT (total n=149 patients) for treating pressure ulcers in any care setting, although most of the patients were treated in a hospital setting.⁹ Three trials were considered to be at high-risk of bias, and all evidence was considered to be of very low-quality. Only 1 trial reported on complete wound healing, which occurred in only 1 of the 12 study participants. Reviewers concluded there is high uncertainty about the potential benefits and/or harms for this indication.

One representative trial, from 2003 (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.¹⁰ All patients with pelvic pressure ulcers were eligible for enrollment and were not required to be refractory to standard treatment. There was no significant group difference 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 might not have received optimal wound management, and lack of information on the time to complete wound healing.

Section Summary: Chronic Pressure Ulcers

The evidence on outpatient NPWT for chronic pressure ulcers includes RCTs and systematic reviews. However, all trials were of low-quality and at high-risk of bias. Also, most patients were treated in an inpatient setting.

Lower-Extremity Ulcers due to Venous Insufficiency

Clinical Context and Test Purpose

The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with lower-extremity ulcers due to venous insufficiency.

The question addressed in this evidence review is: does NPWT improve outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds; and to assess the evidence on the use of portable NPWT devices?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with lower-extremity ulcers due to venous insufficiency.

Interventions

The therapy being considered is outpatient NPWT.

Comparators

Comparators of interest include compression therapy.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

Timing

Though not completely standardized, follow-up for lower-extremity ulcers due to venous insufficiency symptoms would typically occur in the months to years after starting treatment.

Setting

Patients with lower-extremity ulcers due to venous insufficiency are actively managed by dermatologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

A 2015 Cochrane review of NPWT for venous insufficiency identified a single RCT with 60 patients.¹¹ This trial, published by Vuerstaek et al (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 in duration.¹² Full-thickness punch skin grafts from the thigh were applied, followed by four 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 the 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 would 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.

Section Summary: Lower-Extremity Ulcers due to Venous Insufficiency

A single RCT has been identified on use of NPWT for the treatment of lower-extremity ulcers due to venous insufficiency in the hospital setting. No evidence was identified on treatment in the home setting.

Burn Wounds

Clinical Context and Test Purpose

The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with burn wounds.

The question addressed in this evidence review is: does NPWT improve outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds; and to assess the evidence on the use of portable NPWT devices?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with burn wounds.

Interventions

The therapy being considered is outpatient NPWT.

Comparators

Comparators of interest include standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

Timing

Follow-up at 35 months is of interest for outpatient NPWT to monitor relevant outcomes.

Setting

Patients with burn wounds are actively managed by dermatologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

A 2014 Cochrane review of NPWT for burn wounds identified an interim report (abstract) of an RCT on NPWT in patients with partial-thickness burns.¹³ The abstract did not provide enough evidence to draw any conclusions on the efficacy of NPWT on partial-thickness burn wounds. Not included in the Cochrane review was a trial by Bloemen et al (2012) on the effect of NPWT on graft take in full-thickness burn wounds.¹⁴ This multicenter, 4-armed RCT enrolled 86 patients and 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, the 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.¹⁵

A retrospective case series by Ehrl et al (2017) examined outcomes for 51 patients treated for burned hands with topical negative pressure wound (TNPW) therapy at a single-center; of the initial 51 patients, only 30 patients (47 hands) completed follow-up, which was conducted an average of 35 months after injury and included physical examination.¹⁶ Before TNPW therapy, patients received escharotomy or superficial débridement if needed, or split-thickness skin grafts for third-degree burns and the TNPW gloves used allowed caregivers to assess patients' fingertips for perfusion. Ergotherapy was initiated following evidence of epithelialization. Primary endpoints were a dorsal extension of the fingers and capability of complete active fist closure, with the majority of patients achieving one or both outcomes: the first endpoint was reached in 85.1% (n=40) of the cases; the second endpoint was reached in 78.7% of hands (n=37). When evaluated using the Disabilities of the Arm, Shoulder, and Hand questionnaire (scoring range, 0-100; with 0=no disability), patients with injuries resulting in hypertrophic scarring had significantly worse scores (28.8) than patients without similar scarring (11.7; p<0.05). Despite a number of limitations, including heterogeneity of burned areas (2.5% to 70% throughout the series), the authors acknowledged TNPW therapy as standard treatment at the institution from which these data were drawn.

Section Summary: Burn Wounds

The evidence on NPWT as a primary treatment of partial-thickness burns is limited. A retrospective case series reported functional outcomes in most patients treated for hand burns with NPWT. One RCT on NPWT for skin grafts showed no benefit for graft take, wound epithelialization, or scar quality.

Traumatic and Surgical Wounds

Clinical Context and Test Purpose

The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with traumatic or surgical wounds.

The question addressed in this evidence review is: does NPWT improve outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds; and to assess the evidence on the use of portable NPWT devices?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with traumatic or surgical wounds.

Interventions

The therapy being considered is outpatient NPWT.

Comparators

Comparators of interest include standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

Timing

Follow-up at 113 days is of interest for outpatient NPWT to monitor relevant outcomes.

Setting

Patients with traumatic or surgical wounds are actively managed by dermatologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Identified studies have described various wound types treated over periods ranging from several days to several months. Studies also differed by 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.¹⁷ 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 (total n=785 patients) were included in the review. Three trials involved skin graft patients, four included orthopedic patients, and two included general surgery and trauma surgery patients. All trials had an unclear or high-risk of bias. There were no differences between standard dressing and NPWT for 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 appeared to have used short-term application of NPWT in an inpatient setting.

A 2015 Cochrane review evaluated the effects of NPWT on surgical wound healing by secondary intention in any care setting.¹⁸ 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 outcomes data on the number of wounds healed, adverse events, and resource use. Reviewers concluded that there was currently no rigorous RCT evidence available on the clinical effectiveness of NPWT in the treatment of surgical wounds healing by secondary intention.

A systematic review and meta-analysis by De Vries et al (2016) included 6 RCTs and 15 observational studies of surgical site infections after prophylactic NPWT.¹⁹ One study selected used a portable device (PICO, described below), while the others used a V.A.C. Unlike the 2014 Cochrane review, studies on skin grafts were not included. Meta-analysis of the RCTs showed that use of NPWT reduced the rate of surgical site infections (odds ratio, 0.56; 95% CI, 0.32 to 0.96; p=0.04), and reduced the surgical site infection rate from 140 to 83 per 1000 patients. However, the quality of evidence was rated as low due to high-risk of bias in the nonblinded assessments and imprecision in the estimates.

Table 1. Summary of Key RCTs of NPWT vs. Standard Closure in Surgical Wounds

Study	Surgery Received	No. of Participants	Notes on NPWT effectiveness	P value
Stannard et al (2012)	Various, after fractures and other trauma	249	Fewer infections, less discharge than standard closure	0.049
Masden et al (2012)	Various	81	No significant differences in infection or healing	NR
Chio and Agrawal (2010)	Radial forearm donor site	43	No significant differences in wound complications or graft failure	NR
Javed et al (2018)	Open pancreaticoduodenectomy	123	9.7% of NPWT group developed infections, compared with 31.1% of standard closure group	0.003
Sahebally et al (2018)	Bilateral breast reduction mammoplasty	32	Patients used as own control; NPWT associated with significantly lower risk of complication and improved pain and scarring compared with fixation strips	0.004

The largest study 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.²⁰ (A preliminary report was published in 2006.²¹) 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 trial participants 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 (the difference was not statistically significant). The NPWT group had significantly fewer infections (10% of fractures) than the control group (19% of fractures; $p=0.049$). Wound dehiscence after discharge was observed less frequently in the NPWT group (8.6%) than in the control group (16.5%). These results would support the efficacy of the short-term use of NPWT when used under highly controlled conditions of inpatient care, but not the effectiveness of NPWT in the outpatient setting. A small 2015 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 with standard wound care.²²

Other randomized studies have reported no benefit for 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.²³ At a mean of 113 days follow-up, there were no significant differences in the proportions 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 the healing of the radial forearm free flap donor site.²⁴ There were no statistically significant differences in wound complications or graft failure (percentage of area for graft failure, 7.2% for negative pressure vs 4.5% for standard dressing). Biter et al (2014) found no significant advantage of 2 weeks of NPWT in 49 patients who underwent surgical excision for pilonidal sinus disease.²⁵ Complete wound healing was achieved at a median of 84 days in the NPWT group and 93 days in controls.

Danne et al (2017) published a retrospective study comparing NPWT with alginate-based or gauze daily dressing, using data from 73 patients who were treated between 2006 and 2015 for natal cleft pilonidal sinus.²⁶ Most patients ($n=62$) were assigned open healing following surgery, and 9 patients with wounds smaller than 1 cm had primary closure. The primary outcomes of interest were time to healing and, where applicable, failure to heal. For the former, patients in the daily dressing group took a median of 10 weeks (95% CI, 7 to 17 weeks) to heal, compared with 8 weeks (95% CI, 7 to 9 weeks) in the NPWT group. This difference ($p=0.116$) was not statistically significant, as was the difference between groups for recurrence of the pilonidal sinus (12.5% of the daily dressing group vs 3.1% of the NPWT group had disease recurrence, $p=0.355$); however, investigators noted that both outcomes were favorable for the NPWT group. In subgroup analysis of patients with comorbidities vs those without, there was a significantly improved likelihood of healing for the latter; given the presence of comorbidities such as previous pilonidal sinus surgery, infective skin conditions, morbid obesity, or type 1 diabetes, patients with such risks had a hazard ratio of 13.10 (95% CI, 3.90 to 44.04) compared with those free of comorbidities ($p<0.001$). While a number of patients were lost to follow-up, of those at the final analysis, 72.4% in the daily dressing group reached epithelialization, compared

with 93.6% in the NPWT group, prompting investigators to call for larger prospective studies of the intervention.

Mir et al (2018) performed a systematic review with meta-analysis to evaluate the utility of NPWT on head and neck wounds. Researchers searched five databases and found 57 articles with a pooled patient sample of 522 for inclusion in the study. The analysis determined that, across all studies, 85.7% of patients overall responded to NPWT (95% CI: 80.6%-89.6%; $p < 0.001$). The review is limited because all included studies were observational in nature and had a small pooled sample size relative to the number of studies.²⁷

Javed et al (2018) conducted a single-site RCT to evaluate the efficacy of NPWT for surgical site infection after an open pancreaticoduodenectomy. Researchers randomized 123 patients treated from January 2017 through February 2018 to either NPWT (n=62) or standard closure (n=61). In the study, 9.7% of patients who received NPWT developed a postoperative infection at the site, compared with 31.1% of patients who received standard closure, a relative risk of 0.31 (95% CI: 0.13-0.73; $p = 0.003$). Limitations of the study included being conducted at a high-volume treatment center and a lack of blinding.²⁸

Sahebally et al (2018) performed a systematic review with meta-analysis to evaluate the effects of NPWT on surgical site infections in closed laparotomy incisions. Researchers searched four databases through December 31, 2017, and screened bibliographies of retrieved studies to find further studies; nine unique studies (3 RCTs, 2 prospective studies, and 4 retrospective studies) representing 1266 unique patients were included in the review. The analysis determined that NPWT was associated with a significantly lower rate of surgical site infection compared with standard wound dressing (pooled odds ratio: 0.25; 95% CI: 0.12-0.52; $p < 0.001$). The review was limited by including mostly non-randomized studies and use of different NPWT devices.²⁹

Tanaydin et al (2018) conducted an RCT to compare NPWT to standard wound care after a bilateral breast reduction mammoplasty. In the study, 32 patients were given NPWT on one breast and fixation strips on the other, simultaneously serving as study group and control group. Sites treated with NPWT showed a significantly lower rate of complications ($p < 0.004$) compared to fixation strips, as well as improved pain and scarring. Limitations included the small sample size and lack of blinding.³⁰

Section Summary: Traumatic and Surgical Wounds

The evidence on the use of NPWT for individuals who have traumatic or surgical wounds includes RCTs and systematic reviews. 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 for any wound outcome measure. However, a small RCT suggested that prophylactic NPWT might reduce the number of dressing changes and pain when used in an outpatient setting. A small retrospective study reported improved epithelialization in patients free of comorbidities treated with NPWT. Additional study in a larger sample is needed to evaluate this outcome measure.

Portable Single-Use NPWT Devices for Any Wound Type (Acute and Nonhealing)Clinical Context and Test Purpose

The purpose of portable single-use outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with any wound type (acute or nonhealing).

The question addressed in this evidence review is: does NPWT improve outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds; and to assess the evidence on the use of portable NPWT devices?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with any wound type (acute or nonhealing).

Interventions

The therapy being considered is portable single-use outpatient NPWT.

Comparators

Comparators of interest include standard NPWT.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

Timing

Follow-up at 30 days is of interest for portable single-use outpatient NPWT to monitor relevant outcomes.

Setting

Patients with any wound type (acute or nonhealing) are actively managed by dermatologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

SNaP Wound Care System

The portable, nonpowered (mechanical) gauze-based 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.

Armstrong et al (2011) reported on results of a planned interim analysis of an RCT comparing the SNaP Wound Care System with the V.A.C. Therapy for the treatment of chronic lower-extremity wounds.³¹ Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.³² The trial enrolled 132 patients with lower-extremity venous or diabetic ulcers with a surface area between 1 cm² and 100 cm² and diameter less than 10 cm present for more than 30 days despite appropriate care having. Dressings were changed per the manufacturer's direction: two times per week in the SNaP group and three times per week in the V.A.C. group. Patients were assessed for up to 16 weeks or until complete wound closure; 83 (63%) patients 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 two 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 with the SNaP device and use of the SNaP device interfered less with mobility and activity than the V.A.C. device. Subgroup analysis (2015) of 40 patients with venous leg ulcers who completed the study showed a significant improvement in the percentage of those with complete wound closure treated with SNaP(57.9%) compared with the V.A.C. system (38.2%; p=0.008).³³ This study had a high loss to follow-up and lacked a comparison with standard treatment protocols.

A 2010 retrospective study with historical controls compared NPWT using the SNaP device (n=28) with wound care protocols using Apligraf, Regranex, and skin grafting (n=42) for the treatment of lower-extremity ulcers.³⁴ Seven (25%) patients in the SNaP-treated group could not tolerate the treatment and were discontinued from the study because of complications; they 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, multiple modalities to treat controls, and a large number of dropouts. The authors noted that patients in the SNaP-treated group might 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 two sterile dressings and has a lifespan of seven days. Karlakki et al (2016) reported on an RCT with 220 patients that evaluated the use of the PICO device in a surgical center immediately after hip and knee arthroplasties.³⁵ The device was left on for seven days, including the time after the hospital stay. Strengths of the trial included power and intention-to-treat analysis, but evaluators were not blinded. There were trends toward reductions in hospital length of stay (0.9 days; 95% CI, -0.2 to 2.5 days; p=0.07) and postoperative surgical wound complications (8.4% control vs 2.0% PICO, p=0.06). However, most of the difference in length of stay was due to wound complications in 2 outliers in the control group (up to 61 days). The level of wound exudate was significantly reduced by the PICO device (p=0.007), with 4% of the study group and 16% of the

control group having grade 4 (scale grade, 0-4) exudate. Blisters were observed in 11% of patients treated with the PICO system, although the blister occurrence was reported to be reduced when the dressing was stretched less.

Schwartz et al (2015) reported on an industry-funded pilot study assessing 12 patients who had small wounds of various types (total, 13 wounds).³⁶ A key selection criterion was a complete failure to progress over the previous four weeks. During the four 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 the skin graft donor sites.

O'Leary et al (2017) published an RCT that allocated 50 patients to standard wound dressing or negative pressure wound dressing after abdominal surgery; patients had class I, II, or III wounds, and the treatment group was given the PICO dressing.³⁷ Surgical site infection was evaluated at 4 and 30 days following surgery, and results were analyzed both on per-protocol and intention-to-treat bases. Caregivers did not find a significant difference between groups after 4 days ($p=0.516$); however, at the 30-day follow-up, rates of surgical site infections were significantly lower for the group receiving negative pressure dressing than for the control group, both in per-protocol analysis (8.3% vs 32.0%, $p=0.043$) and intention-to-treat analysis (12% vs 32%, $p=0.073$). Univariate analysis showed a significant association between standard wound dressing and the likelihood of a surgical site infection ($p=0.040$); for secondary outcomes (eg, cosmetic outcome, patient satisfaction), the authors reported no difference between groups. The mean length of stay was shorter for patients who received negative pressure dressings (6.1 days) than for control patients; however, when all reasons for delayed discharge were accounted for, the difference was not statistically significant ($p=0.89$). While comparatively small, this trial would indicate that negative pressure dressings resulted in a beneficial outcome for patients recovering from abdominal surgery regarding the occurrence of surgical site infections.

Prevena System

Prevena is a single-use NPWT system designed specifically for incisions. Grauhan et al (2013) reported on a pseudorandomized trial (alternating assignment) with 150 consecutive obese patients who underwent cardiac surgery via a median sternotomy.³⁸ Use of the Prevena System for 6 to 7 days beginning immediately after suturing reduced rates of wound infection (4%) compared with standard wound care (4 16%; $p=0.027$). Gram-positive skin flora was found in one patient in the Prevena group and in ten patients in the wound care group. This study was performed in an inpatient setting. A randomized trial (NCT02195310) involving a larger number of patients with sternal midline incisions was terminated in early 2017.

Pauser et al (2016) reported on a small RCT ($n=21$) evaluating Prevena in patients who had hemiarthroplasty for femoral neck fractures.³⁹ Use of the Prevena System significantly reduced seroma size, days of wound secretion, wound care time, and need for dressing changes.

Section Summary: Portable Single-Use NPWT Devices for Any Wound Type

The evidence on portable single-use NPWT includes an RCT of the PICO device, an RCT of the nonpowered SNaP System, and a pseudorandomized study of the Prevena Incision Management System. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use after total joint arthroplasty; also, a 2017 RCT compared the PICO device with standard dressing following abdominal surgery. Results showed some potential benefits but

were not statistically significant. Further study in an outpatient setting is needed. One study of the SNaP 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. The evidence base for the Prevena System is not sufficiently robust for conclusions on efficacy to be drawn. Well-designed comparative studies with larger numbers of patients are needed.

SUMMARY OF EVIDENCE

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive outpatient NPWT, the evidence includes RCTs and a systematic review of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There was a higher rate of wound healing and fewer amputations with NPWT, although the studies were at risk of bias due to lack of blinding. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have chronic pressure ulcers who receive outpatient NPWT, the evidence includes For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive outpatient NPWT, the evidence includes randomized controlled trials (RCTs) and a systematic review of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There was a higher rate of wound healing and fewer amputations with NPWT, although the studies were at risk of bias due to lack of blinding. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have chronic pressure ulcers who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. The 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. Also, most study populations were treated in inpatient settings. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lower-extremity ulcers due to venous insufficiency who receive outpatient NPWT, the evidence includes an RCT and a systematic review. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. A single RCT in patients with nonhealing leg ulcers who were treated with skin grafts found a faster rate of healing with NPWT when used in the inpatient setting. No studies were identified on the effectiveness of NPWT as a primary treatment for leg ulcers or for the use of NPWT in the outpatient setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have burn wounds who receive outpatient NPWT, the evidence includes RCTs, systematic reviews, and case series. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. An interim report of an RCT evaluating NPWT in partial-thickness burns, summarized in a Cochrane review, did not permit conclusions on the efficacy of NPWT for this indication. A separate RCT comparing NPWT with split-skin grafts in patients with full-thickness burns did not show differences in graft take and wound epithelialization. A retrospective case series reported functional outcomes for most patients who were treated with NPWT at a single-center. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have traumatic or surgical wounds who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. The 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 in 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 for any wound outcome measure. However, a small RCT has suggested that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. A small retrospective study reported improved epithelialization with NPWT in patients free of comorbidities. Additional study in larger samples is needed to evaluate this outcome measure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have any wound type (acute or nonhealing) who receive portable single-use outpatient NPWT, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The evidence includes an RCT of the PICO Single Use Negative Pressure Wound Therapy System, an RCT of the nonpowered Smart Negative Pressure Wound Care System, and a pseudorandomized study of the Prevena Incision Management System. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use following total joint arthroplasty; also, a 2017 RCT compared the PICO device with standard dressing following abdominal surgery. Results showed some benefits, though not statistically significant. One study with the Smart Negative Pressure nonpowered Wound Care System showed noninferiority to a vacuum-assisted closure device. However, interpretation of this trial is limited by a high loss to follow-up and lack of a control group treated with dressings. These studies are insufficient to draw conclusions about its efficacy. Well-designed comparative studies with larger numbers of patients are needed to determine the effects of these technologies with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

Overall, the evidence from comparative clinical trials has demonstrated 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.

CLINICAL INPUT 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.

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 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.⁴⁰ The panel made the following recommendations for the use of NPWT (see Table 2).

Table 2. Recommendations on Use of NPWT in Chronic Wounds

Condition	Recommendation	Grade
Pressure ulcers, grade 3-4	"NPWT may be used until surgical closure is possible/desirable"	C
	"NPWT should be considered to achieve closure by secondary intention.... to reduce wound dimensions... [and] to improve the quality of the wound bed."	B
Diabetic foot ulcers	"NPWT must be considered as an advanced wound care therapy.... [and] must be considered to achieve healing by secondary intention."	A
	"NPWT should be considered in an attempt to prevent amputation or reamputation."	B
Ischemic lower-limb wounds	"... NPWT ... may be considered in specialist hands and never as an alternative for revascularisation."	C
	"... NPWT is NOT indicated in acute limb ischemia."	D
Venous leg ulcers	"If first line therapy (compression) is not efficacious, NPWT should be considered to prepare the wound for surgical closure...."	B

NPWT: negative pressure wound therapy.

^a Grade A: based on high-quality meta-analyses, systematic reviews of randomized controlled trials, or randomized controlled trials with very low risk of bias; grade B: based on high-quality systematic reviews of case-control or cohort studies; grade C: based on well-conducted case-control or cohort studies; grade D: based on case series or expert opinion.

International Multidisciplinary Consensus Recommendations

In 2017, Willy et al presented evidence-based consensus guidelines on the use of closed incision negative pressure therapy (ciNPT) following surgery.⁴¹ Among the studies found were 100 randomized controlled studies on ciNPT, most of which found an association between the use of ciNPT and improved outcomes. Based on the evidence, the consensus panel recommended that surgeons evaluate risk in patients before surgery to determine whether patient comorbidities (ie, obesity or diabetes) or the nature of the surgery presents an increased danger of infection. In such cases, the panel recommended the use of ciNPT.

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.⁴² 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).

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 negative wound therapy (weak recommendation, low quality evidence).⁴³

American College of Physicians

In 2015, the American College of Physicians (ACP) published guidelines on the treatment of pressure ulcers.⁴⁴ The guidelines stated that there was low-quality evidence that the overall treatment effect of NPWT did no differ from standard of care.

Association for the Advancement of Wound Care

In 2010, the Association for the Advancement of Wound Care (AAWC) published guidelines on care of pressure ulcers.⁴⁴ NPWT was included as a potential second-line intervention if first-line treatments did not result in wound healing (level B evidence). The guidelines indicated that patients must be selected carefully for this procedure. The guidelines were updated in 2014 with additional validation.⁴⁵

In 2010, AAWC also issued guidelines on care of venous ulcers.⁴⁶ The guidelines listed NPWT as a potential adjunctive therapy if conservative therapy does not work in 30 days. The guidelines noted that there is limited evidence for NPWT (level B) compared to other adjunctive therapies.

National Institute for Health and Clinical Excellence

The U.K.'s National Institute for Health and Clinical Excellence (NICE) 2013 guidance on NPWT for surgical wounds concluded that "Current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen is adequate to support the use of this procedure."⁴⁷

A 2015 NICE guidance on diabetic foot problems, updated in 2016, recommends consideration of NPWT after surgical debridement for diabetic foot ulcers on the advice of the multidisciplinary foot care service.⁴⁸ 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.

In 2014, NICE issued a guidance on the prevention and management of pressure ulcers.⁵¹ The guidance states "Do not routinely offer adults negative pressure wound therapy to treat a pressure ulcer, unless it is necessary to reduce the number of dressing changes (for example, in a wound with a large amount of exudate)." In addition, the guidance did not recommend NPWT for neonates, infants, or children.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02127281 ^a	Randomized Controlled Trial of Wound Management With Negative Pressure Dressing Versus Standard Dressing After Knee and Hip Revision Arthroplasty	160	Jun 2017 (ongoing)
NCT02020018 ^a	Negative Pressure Wound Therapy for Prevention of Wound Infection After Heart Surgery	950	Dec 2017 (ongoing)
NCT02739191	Negative Pressure Wound Therapy for Surgical Wounds of the Foot and Ankle	60	Aug 2017 (ongoing)
NCT02007018	Negative Pressure Wound Therapy Use to Decrease Surgical Nosocomial Events in Colorectal Resections (NEPTUNE)	300	Sep 2017 (ongoing)
NCT02461433 ^a	The SAVIOR Trial: Surgical Application of Vac Dressings In Obese Patients to Reduce Wound Complications	108	Terminated
NCT02470806 ^a	A Prospective, Randomized, Comparative Effectiveness Study of a Single-Use, Negative Pressure Wound Therapy System (PICO) Versus a Traditional Negative Pressure Wound Therapy System (tNPWT) in the Treatment of Lower Extremity Ulcers	163	Nov 2017 (ongoing)
NCT02664168	A Prospective, Randomized, Comparative Study to Assess the Prevention of Surgical Site Infection (SSI's) in Revision Total Joint Arthroplasty Patients Treated With Single-Use Negative Pressure Wound Therapy (PICO™) or Standard Care Dressings (AQUACEL® Ag SURGICAL Dressing)		Feb 2020
NCT01528033 ^a	Treatment Study of Vacuum Assisted Closure for Postsurgical Subcutaneous Abdominal Wound Healing Impairments (SAWHI)	550	Jun 2018
NCT02309944	Negative Pressure Wound Therapy in Obese Gynecologic Oncology Patients	200	Dec 2019
NCT02509260	Prevena™ Incisional Negative Pressure Wound Therapy in Re-operative Colorectal Surgery	298	Dec 2018
NCT02799667	Randomized Controlled Trial: Do Single Use Negative Pressure Dressings Reduce Wound Complications in Women With a BMI >40 kg/m ² Undergoing Cesarean Delivery at a Tertiary Medical Center?	242	May 2019
NCT01913132	PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - a Prospective Randomized Trial	644	Apr 2020
NCT02348034 ^a	A Randomized Controlled Trial Exploring the Ability of Negative Pressure Wound Therapy (NPWT) to Reduce Colorectal Surgical Site Infections (SSI)	398	Jul 2019
NCT02954835	Negative Pressure Therapy for Closed Groin Wounds in Patients Undergoing Vascular Surgery	100	Dec 2019 (estimated)
NCT02467998	The Registry of Negative Pressure Wound Therapy for Chronic Wounds and Ulcers	50,000	Jan 2020
NCT03144726	Single Center Prospective Randomized Control Trial on Negative Pressure Wound Therapy for Incisions Following Major Lower-limb Amputation to Reduce Surgical Site Infection	290	Jul 2020
NCT02682316 ^a	A Phase III Randomized Controlled Trial of Negative Pressure Wound Therapy in Post-Operative Incision Management	686	Feb 2021
NCT01821664	Vascular Graft Infections - Epidemiology, Best Treatment Options, Imaging Modalities and Impact of Negative Pressure Wound Therapy	1800	Mar 2023
NCT02813161	A Real World, Observational Registry of Diabetic Foot Ulcers and Quality of Care in Clinical Practice	10,000	Feb 2025
Unpublished			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01191567	Negative Pressure Wound Therapy. Therapy Effects and the Impact on the Patient's Quality of Life	200	Terminated
NCT02395159	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)	204	Oct 2017 (unknown)
NCT02289157 ^a	Negative Pressure Wound Therapy in High Risk Patients Undergoing Cesarean	441	Oct 2016 (unknown)
NCT02195310 ^a	The Use of Prevena™ Incision Management System on Clean Closed Sternal Midline Incisions in Subjects at High Risk for Surgical Site Occurrences	341	Terminated
NCT02064270 ^a	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 Dressings	526	Sep 2017 (unknown)
NCT01890720 ^a	Use of Incisional Negative Pressure Wound Therapy for Prevention of Postoperative Infections Following Caesarean Section in Women With BMI ≥ 30	856	Dec 2016 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 97605 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 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
- A9272 Wound suction, disposable, includes dressing, all accessories and components, any type, 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

- The following HCPCS code was developed for a disposable NPWT system (eg, the SNaP® or PICO™ systems): A9272.
- The following HCPCS codes were developed specific to a NPWT system (such as the Kalypto® system), in which the exudate is collected in the dressing rather than in a canister: K0743, K0744, K0745, K0746.
- There are 2 CPT codes for application of NWPT utilizing durable medical equipment: 97605, 97606.
- The following HCPCS codes describe NWPT using an electrical pump: A6550, E2402.
- There are also CPT codes for application of NPWT utilizing disposable, nondurable equipment: 97607, 97608.

DIAGNOSES

An appropriate ICD-10 diagnosis code describing the wound that is being treated should be used when reporting vacuum-assisted wound closure.

REVISIONS

August 3, 2006 with effective date of December 1, 2006	In "Policy" 1., 5 th bullet, deleted "(i.e., diabetic ulcers with no presence of infection)" and added "or diabetic lower extremity ulcer" at Medical Directors request.
	In "Policy" 2., added new 'g' For patients awaiting hospital discharge, a 5-day 'evaluation period' may be allowed if sufficient records cannot timely be provided to determine medical necessity. The purpose of this 'evaluation period' is to avoid prolonging the hospital stay while awaiting wound vac decision; and new 'h' VAC approved may be allowed up to 4 weeks before re-review at Medical Directors request.
	In "Policy" 3., d., added new statement "Maximum duration of VAC approval is 4 months. Refer to consultant beyond 4 months." at Medical Directors request.
	In "Policy" section added "Negative pressure therapy post skin grafting is considered experimental/investigational" at Medical Directors request.
	In "Policy" section deleted statement "NOTE: The VAC System may be used in certain cases prior to the 30 days of conservative therapy (i.e., large incisional hernia repair with mesh and diabetic ulcers with no presence of infection) and will be reviewed." at Medical Directors request.

	In "Reference" Government Agency; Medical Society; and Other Authoritative Publications section added "Managing Care Managing Claims (MCMC), July 7, 2006, PRA Case Number - 10706101 at Medical Directors request.
February 7, 2007 with effective date of February 7, 2007, posted March 30, 2007	In "Policy" section deleted #4, "Negative pressure therapy post skin grafting is considered experimental/investigational." at Medical Directors request.
	In "Policy" section added new #4 "Negative pressure therapy post skin grafting will be reviewed by a plastic surgeon consultant to determine necessity based on the size and severity of the wound." at Medical Directors request.
	In "Reference" Government Agency; Medical Society; and Other Authoritative Publications section added "BCBSKS Medical Consultant, MCMC, (Reviewer ID R-W090, MCOP ID 1072-0274), October 23, 2006 at Medical Directors request.
	In "Reference" Government Agency; Medical Society; and Other Authoritative Publications section added BCBSKS Medical Consultant, Practicing Board Certified General Surgeon (249), January 4, 2007 at Medical Directors request.
	In "Reference" Government Agency; Medical Society; and Other Authoritative Publications section added BCBSKS Medical Consultant, Practicing Board Certified Pediatric Surgeon (236), February 5, 2007 at Medical Directors request.
May 8, 2007 with effective date June 15, 2007	In "Policy", deleted the sentence under policy guideline section #2, letter g. "For patients awaiting hospital discharge, a 5-day 'evaluation period' may be allowed if sufficient records cannot timely be provided to determine medical necessity. The purpose of this 'evaluation period' is to avoid prolonging the hospital stay while awaiting wound vac decision".
01-30-2012	In the Coding section: <ul style="list-style-type: none"> Added HCPCS code: A9272 (effective 1/1/2012).
	In the Reference section: <ul style="list-style-type: none"> Removed "Government Agency; Medical Society; and Other Authoritative Publication" and inserted "Other References."
01-01-2015	Policy posted to the website February 10, 2014.
	In Coding section: <ul style="list-style-type: none"> Added CPT Codes: 87607, 87608 (Effective January 1, 2015) Added HCPCS Codes: K0743, K0744, K0745, K0746 (coding section correction) Revised CPT Codes: 97605, 97606 (Effective January 1, 2015) Revised HCPCS Codes: A6550, A7272 (coding section correction)
04-30-2015	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> Added to Item B (was previously Item 4), "... considered medically necessary for up to 2 weeks. Continuation beyond will be reviewed on a case by case basis," and removed "reviewed by a plastic surgeon consultant to determine necessity based on the size and severity of the wound." to read, "VAC therapy post skin grafting will be considered medically necessary for up to 2 weeks. Continuation beyond will be reviewed on a case by case basis." Added Item C, "Post breast reduction surgery, VAC is considered medically necessary if the patient's BMI is 40 or more. Approval length: 1 week. Added Item D, "Post surgical VAC placement on new or acute wounds will be reviewed on a case by case basis." In Item E, removed "or experimental / investigational in the home setting." to read "All other applications for VAC therapy are considered not medically necessary." In Policy Guidelines, added Item d, "The wound depth is at least 1 mm or greater. Wounds with a depth of <1 mm cannot accommodate the sponge / foam."
	Added Rationale section.

	In Revision section from date 01-01-2015: <ul style="list-style-type: none"> ▪ Revision of Added CPT Codes: "87607, 87608;" to read "97607, 97608" ▪ Revision of Revised HCPCS Codes: "A7272," to read "A9272"
	Updated References section.
03-02-2016	Updated Description section.
	Updated Rationale section.
	In Coding section: <ul style="list-style-type: none"> ▪ Revised coding bullets.
	Updated References section.
02-15-2017	Updated Description section.
	Updated Rationale section.
	In Coding section: <ul style="list-style-type: none"> ▪ Updated coding bullets.
	Updated References section.
06-23-2017	In Policy section: <ul style="list-style-type: none"> ▪ Added new Item D, "Non-electric vacuum assisted wound therapy (eg, SNaP™ Wound Care Device) is considered experimental / investigational for all conditions." ▪ Added new Item E, "Portable, battery-powered, single-use (disposable) vacuum assisted wound therapy devices (eg, the PICO™ Single Use Negative Pressure Wound Therapy System or the V.A.C. Via™ Negative Pressure Wound Therapy System) are considered experimental / investigational for all conditions."
	Updated References section.
02-15-2018	Updated Description section.
	Updated Rationale section.
	Updated References section.
02-18-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.

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