Medical Policy

BlueCross BlueShield Kansas
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Title: Negative Pressure Wound Therapy

Related Policies:	▪ *Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non–Orthopedic Conditions* ▪ *Bio-Engineered Skin and Soft Tissue Substitutes*

Professional / Institutional
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Populations	Interventions	Comparators	Outcomes
Individuals: • With diabetic lower-extremity ulcers or amputation 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:	Interventions of interest are:	Comparators of interest are:	Relevant outcomes include:

Populations	Interventions	Comparators	Outcomes
• With diabetic lower-extremity ulcers or amputation wounds	• Portable, single-use outpatient negative pressure wound therapy	• Standard wound care • Standard negative pressure wound therapy	• Symptoms • Change in disease status • Morbid events • Quality of life • Treatment-related morbidity
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: • Standard wound care • Compression therapy	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: • Portable, single-use outpatient negative pressure wound therapy	Comparators of interest are: • Standard wound care • Compression therapy • Standard negative pressure wound 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 traumatic or surgical wounds	Interventions of interest are: • Portable single-use outpatient negative	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events

Populations	Interventions	Comparators	Outcomes
	pressure wound therapy	• Standard negative pressure wound therapy	• Quality of life • Treatment-related morbidity

DESCRIPTION

Negative pressure wound therapy (NPWT) involves the use of negative pressure or suction devices 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 evidence review 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, single-use negative pressure wound therapy devices.

BACKGROUND

CHRONIC WOUNDS

Management

The management and treatment of chronic wounds, including decubitus ulcers, is challenging. Furthermore, certain racial and ethnic groups, including African Americans, Hispanics, and Native Americans, experience higher diabetes prevalence, contributing to disparities in the risk for diabetic ulcers; these disparities are exacerbated when inequalities in access to health care result in delayed diagnosis and management.

Most chronic wounds will heal only if the underlying cause (ie, venous stasis, pressure, infection) is addressed. Also, cleaning the wound to remove nonviable tissue, microorganisms, and foreign bodies is essential to create 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, debridement, irrigation, whirlpool treatments, and wet-to-dry dressings are common components of chronic wound care.

Negative pressure wound therapy (NPWT) involves 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 Wound Care System 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 the 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 treating chronic wounds include, but are not limited to: Vacuum-Assisted Closure® Therapy (V.A.C., also known as negative pressure wound therapy; 3M™/KCI); Versatile 1™ (V1) Wound Vacuum System (Blue Sky Medical), RENASYS™ EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical Electronics), SVED® (Cardinal Health), 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), the V.A.C. Via™ (KCI), NPWT PRO to GO (Cardinal Health), 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 (now SNAP™ Therapy System) (3M™/ previously Spiracur, acquired by Acelity in 2015), was cleared for marketing by the FDA in 2009 through the 510(k) pathway (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers.

Negative pressure wound therapy devices with instillation include the V.A.C. VERAFLO™ Therapy device (3M™/KCI/Acelity). It was cleared for marketing in 2011 by the FDA through the 510(k) pathway (K103156) and is designed to allow for controlled delivery and drainage of topical antiseptic and antimicrobial wound treatment solutions and suspensions. It is to be used with the V.A.C. Ulta unit, which is commercially marketed for use in the hospital setting. Instillation is also available with Simultaneous Irrigation™ Technology tubing sets (Cardinal Health) for use with Cardinal Health SVED® and PRO NPWT devices, however, its use is not indicated for use in a home care setting (K161418).

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

In November 2009, the 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

A. Vacuum Assisted Wound Closure (VAC) is considered **medically necessary** to promote the closure of chronic wounds, when progressive wound healing has failed following 30 days of conservative wound treatment **AND ONE** of the following chronic wound conditions is present:
   1. Pressure ulcers – Stage III or Stage IV, **OR**
   2. Venous or arterial insufficiency ulcers, **OR**
   3. Neuropathic ulcers, **OR**
   4. diabetic lower extremity ulcer
      AND
   5. Individual selection criteria have been met (see Policy Guidelines)

B. Vacuum Assisted Wound Closure (VAC) is considered **medically necessary** in acute traumatic or post-surgical wounds, when **ONE** of the following acute wound conditions is present:
   1. Dehisced wounds, **OR**
   2. Wounds with exposed hardware or bone, **OR**
   3. Foreign material within the wound, **OR**
   4. Complications of a surgically created (i.e., large incisional hernia with mesh) or traumatic wound where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment, **OR**
   5. Post sternotomy wound infection or mediastinitis

C. 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.

D. Post breast reduction surgery, VAC is considered **medically necessary** if the individual's BMI is 40 or more. Approval length: 1 week.

E. Non-electric vacuum assisted wound therapy (e.g., SNaP™ Wound Care Device) is considered **experimental / investigational** for all conditions.

F. Portable, battery-powered, single-use (disposable) vacuum assisted wound therapy devices (e.g., 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.

G. All other applications for VAC therapy are considered **not medically necessary**.

POLICY GUIDELINES

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.

Individual Selection Criteria

A. The criteria listed below, as items a. through f. must be met for all conditions:
    1. The wound has been debrided and is free of all the following:
        a. Nonviable or necrotic tissue (eschar)
        b. Macroscopic contamination
        c. Non-enteric and unexplored fistulae
        d. Malignant or metastatic cells
        e. Active bleeding
        f. Pressure on wound
    2. The wound does NOT contain exposed arteries or veins
    3. The individual is free from active osteomyelitis
    4. The wound depth is at least 1 mm or greater. Wounds with a depth of <1 mm cannot accommodate the sponge / foam.
    5. The medical record documents that the individual is NOT nutritionally compromised, or if nutritionally compromised, the medical record documents appropriate interventions have been implemented.
    6. The medical record documents that the individual is willing and able to comply with using continuous or intermittent VAC application 22 of 24 hours per day.
    7. The additional criteria listed below must be met for specific wound types and treatment regimens:
        a. Neuropathic ulcers:
        The individual 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.
        b. Venous or arterial insufficiency ulcers:
        The individual has had compressive bandages and/or garment and leg elevation consistently applied and/or utilized under physician supervision and ambulation has been encourages.
    8. VAC approved may be allowed up to 4 weeks before re-review.

Continuation of Treatment

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

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.

RATIONALE
This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through November 22, 2024.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function¾including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to 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 a technology, 2 domains are examined: the relevance and the 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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.

Negative pressure wound therapy 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 Vacuum-Assisted 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 healing are as follows, consistent with guidance from the U.S. Food and Drug Administration (FDA) for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Generally, in a heterogeneous population, the evidence is uncertain for home use of NPWT. 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 3 retrospective cohort studies on diabetic foot ulcers and arterial ulcers, an RCT and 2 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 Therapy Purpose

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

The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is outpatient NPWT, which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators

The following therapies are currently being used to make decisions about the treatment of diabetic lower-extremity ulcers and amputation wounds: standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Though not completely standardized, follow-up for diabetic

lower-extremity ulcers or amputation wound symptoms would typically occur in the months to years after starting treatment.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.
- Studies conducted exclusively in the inpatient setting were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

A 2013 Cochrane review of NPWT for treating foot wounds in patients with diabetes[6,] was updated in 2018 to include 11 RCTs (N=972) with sample sizes ranging from 15 to 341 participants.[7,] Two studies addressed post-amputation wounds and all other studies described treatment of diabetic foot ulcers. Only 1 study comparing NPWT and moist dressings for post-amputation wounds reported a follow-up time (n=162), and a statistically significant improvement in the proportion of wounds healed (risk ratio [RR], 1.44; 95% confidence interval [CI], 1.03 to 2.01) was demonstrated after a follow-up duration of 16 weeks. The median time to healing was 21 days shorter for the NPWT group (hazard ratio [HR], 1.91; 95% CI, 1.21 to 2.99) compared with moist dressings. Data from 3 studies suggest that people with diabetic foot ulcers allocated to NPWT may be at reduced risk of amputation compared to moist dressings (RR, 0.33; 95% CI, 0.15 to 0.70; I^2=0%). 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.

A systematic review by Wynn and Freeman (2019) evaluating NPWT for diabetic foot ulcers reported similar benefits in wound healing and the reduction of amputation incidence.[8,] However, reviewers emphasized limitations in the present body of evidence, including methodological flaws such as the absence of validated tools for the measurement of wound depth and area, lack of statistical power calculations, and heterogeneity in pressure settings employed during therapy.

A systematic review and meta-analysis by Chen et al (2021) evaluating NPWT for diabetic foot ulcers compared to standard care reported a significant improvement in the wound healing rate

with NPWT (odds ratio [OR], 3.60; 95% CI, 2.38 to 5.45; p<.001) based on 6 RCTs representing 536 patients.[9,] No significant difference in the incidence of adverse events was reported between groups (OR, 0.49; 95% CI, 0.10 to 2.42; p=.38). The reviewers noted several limitations in the body of evidence, including lack of blinding, unclear follow-up durations, and heterogeneous pressure settings.

Section Summary: Diabetic Lower-Extremity Ulcers and Amputation Wounds
The evidence on NPWT for diabetic lower-extremity ulcers and amputation wounds includes systematic reviews 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.

PORTABLE, SINGLE-USE THERAPY FOR DIABETIC LOWER-EXTREMITY ULCERS AND AMPUTATION WOUNDS

Clinical Context and Therapy 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 individuals with diabetic lower-extremity ulcers or amputation wounds.

The following PICO was used to select literature to inform this review.

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

Interventions
The therapy being considered is portable, single-use outpatient NPWT (powered or nonpowered), which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators
The following therapies are currently being used to make decisions about the treatment of diabetic lower-extremity ulcers and amputation wounds: standard wound care and standard, reusable NPWT devices.

Outcomes
The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Though not completely standardized, follow-up for diabetic lower-extremity ulcers or amputation wound symptoms would typically occur in the months to years after starting treatment.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.

- Pain control.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.
- Studies conducted exclusively in the inpatient setting were excluded.

REVIEW OF EVIDENCE

PICO Dressing
PICO is a portable, single-use NPWT system that comes with 2 sterile dressings and has a lifespan of 7 to 14 days.

Kirsner et al (2019) published an RCT that allocated 164 patients with venous leg ulcers (n=104) or diabetic foot ulcers (n=60) to treatment with PICO single-use NPWT (s-NPWT; n=80) or traditional, reusable NPWT systems (t-NPWT; n=84).[10,] Prior to randomization, patients were excluded if a reduction in target ulcer area ≥30% was achieved with compression or offloading during a 2-week run-in period as a way to exclude 'quick healers'. Three patients in the t-NPWT arm were excluded from the intention-to-treat analysis. For the per-protocol analysis, 16 (20%) and 30 (37%) patients were excluded from the s-NPWT and t-NPWT arms, respectively. Randomization was stratified by wound type and wound size. The PICO dressing was set to provide -80 mmHg of negative pressure. Choice of traditional, NPWT device manufacturer and pressure setting was at the discretion of the treating physician, with an average pressure of -118.3 mmHg (median, -125 mmHg; standard deviation [SD], 23.4 mmHg) applied.

The study intended to test for noninferiority in the percentage change of target ulcer area with s-NPWT versus t-NPWT over the course of a 12-week treatment period, with a noninferiority margin of 12.5%. The analysis was performed with the per-protocol population to account for dropouts and then repeated on the full analysis set (intention-to-treat). Secondary outcomes included wound closure rate, time to wound closure, and quality of life. Participants and investigators were not blinded, and it is unclear if the study utilized blinded assessors. Patients were seen weekly in outpatient wound centers. After adjustment for baseline wound area, pooled study site, wound type, and wound duration at baseline, the mean percentage difference in wound area over 12 weeks was 27% (96.9% vs. 69.9%; p=.003) in the per-protocol analysis and 39.1% (90.24% vs. 51%; p<.001) in the intention-to-treat analysis. This treatment effect was also significant in the diabetic foot ulcer subgroup (p=.031). However, confidence intervals were not reported for the primary outcome.

Confirmed wound closure (intention-to-treat) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted OR of 0.294 (95% CI, 0.135 to 0.638; p=.002) for all wound types and 0.161 (95% CI, 0.035 to 0.744; p=.020) for diabetic foot ulcer. However,

the subgroup analysis for diabetic foot ulcer patients in the per-protocol population was not significant.

The median estimate of the time to achieve confirmed closure was 77 days for s-NPWT (95% CI, 49 to undefined limit) and could not be calculated for t-NPWT due to the low number of patients achieving this endpoint. No significant differences were noted in health-related QOL between baseline and exit visits. Fifty-seven treatment-related adverse events were reported, 16 related to s-NPWT in 12 patients and 41 related to t-NPWT in 29 patients. Wound-related adverse events included increase in target ulcer size, inability to tolerate NPWT, and periwound skin maceration, resulting in study discontinuation by 3 treated with s-NPWT and 9 treated with t-NPWT. While the PICO dressing met noninferiority, change in wound area is not a primary health outcome of interest due to its inherent heterogeneity. Additionally, the chosen treatment duration may have been of insufficient duration to accurately assess effects on wound closure. Required use of fillers, a higher level of negative pressure, and utilization of devices from various t-NPWT manufacturers may have impacted findings. Only 20% of patients in the s-NPWT arm were treated with fillers, mainly in those with diabetic foot ulcer.

A subanalysis of this RCT highlighting outcomes in patients with lower-extremity (foot and venous leg) diabetic ulcers was published by Kirsner and colleagues.[11,] The intention-to-treat population included 46 patients in the s-NPWT arm and 49 patients in the t-NPWT arm. The treatment OR for achieving confirmed wound closure at 12 weeks was 0.129 (95% CI, 0.041 to 0.404; p<.001). In the per-protocol population, which included 36 patients in the s-NPWT arm and 25 patients in the t-NPWT arm, the treatment OR for confirmed wound closure at 12 weeks was 0.179 (95% CI, 0.044 to 0.735; p=.017). Baseline patient characteristics, including distribution of foot and venous leg ulcers in each treatment arm, were not reported. This analysis is also limited by its retrospective, post-hoc nature and insufficient follow-up duration.

Smart Negative Pressure Wound Care System

The portable, nonpowered (mechanical) gauze-based SNaP Wound Care System (now SNAP therapy 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 the 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.[12,] Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.[13,] The trial enrolled 132 patients with lower-extremity venous or diabetic ulcers with a surface area between 1 cm^2 and 100 cm^2 and diameter less than 10 cm present for more than 30 days despite appropriate care. Approximately 30% of patients in this study had diabetic ulcers, and no subgroup analyses were conducted. 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 (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 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 with the SNaP device and use of the SNaP device interfered less with mobility and activity than the V.A.C. device.

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.[14,] 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. Subgroup analyses for patients with diabetic (50%) and venous (50%) ulcers were not available. 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.

Section Summary: Portable, Single-Use Therapy for Diabetic Lower-Extremity Ulcers and Amputation Wounds
The evidence on portable, single-use NPWT for diabetic ulcers and amputation wounds includes an RCT of the PICO device and an RCT of the nonpowered SNaP System. A 2019 RCT compared the PICO device with standard NPWT in outpatients with diabetic and venous ulcers. In this study, the PICO device demonstrated noninferiority for wound area reduction. A statistically significant benefit in complete wound closure was noted for patients with diabetic ulcers, but was not duplicated in the per-protocol population due to a high number of exclusions. Interpretation of this study is limited by variable device settings and short follow-up duration. One study of the SNaP System showed noninferiority to a V.A.C. device for wound size reduction. No significant difference in complete wound closure was reported. Interpretation of this study is limited by a high loss to follow-up. Well-designed comparative studies with larger numbers of patients powered to detect differences in complete wound closure are needed.

CHRONIC PRESSURE ULCERS

Clinical Context and Therapy Purpose
The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with chronic pressure ulcers.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with chronic pressure ulcers.

Interventions
The therapy being considered is outpatient NPWT, which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators
The following therapies are currently being used to make decisions about the treatment of chronic pressure ulcers: standard wound care.

Outcomes
The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Though not completely standardized, follow-up for chronic pressure ulcers would typically occur in the months to years after starting treatment.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.
- Studies conducted exclusively in the inpatient setting were excluded.

REVIEW OF EVIDENCE

Systematic Reviews
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.[6,] 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. An update of this Cochrane review was published in 2023 and included 8 RCTs (N=327).[15,] However, there were no additional trials that reported on complete wound healing. Reviewers similarly concluded that available evidence is of poor quality and conclusions drawn should be interpreted with considerable caution.

Randomized Controlled Trials
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.[16,] 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 Therapy Purpose
The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with lower-extremity ulcers due to venous insufficiency.

The following PICO was used to select literature to inform this review.

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

Interventions
The therapy being considered is outpatient NPWT, which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators
The following therapies are currently being used to make decisions about the treatment of lower-extremity ulcers due to venous insufficiency: compression therapy and standard wound care.

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]
- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.
- Studies conducted exclusively in the inpatient setting were excluded.

REVIEW OF EVIDENCE

Randomized Controlled Trials

A 2015 Cochrane review of NPWT for venous insufficiency identified a single RCT with 60 patients.[17,]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.[18,] Full-thickness punch skin grafts from the thigh were applied, followed by 4 days of NPWT or conventional care to assure complete graft adherence. Each group then received standard care with nonadhesive dressings and compression therapy until complete healing (primary outcome) occurred. The median time to complete healing was 29 days in the NPWT group and 45 days in the control group (p=.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 the 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.

PORTABLE, SINGLE-USE THERAPY FOR LOWER-EXTREMITY ULCERS DUE TO VENOUS INSUFFICIENCY

Clinical Context and Therapy 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 individuals with lower-extremity ulcers due to venous insufficiency.

The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is portable, single-use outpatient NPWT (powered or nonpowered), which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators
The following therapies are currently being used to make decisions about the treatment of lower-extremity ulcers due to venous insufficiency: compression therapy, standard wound care, and standard, reusable NPWT devices.

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]
- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.
- Studies conducted exclusively in the inpatient setting were excluded.

REVIEW OF EVIDENCE

PICO Dressing
Kirsner et al (2019) published an RCT that allocated 164 patients with venous leg ulcers (n=104) or diabetic foot ulcers (n=60) to treatment with PICO s-NPWT (n=80) or t-NPWT (n=84).[10,] Additional study details and limitations are summarized previously in indication 2.

The primary outcome measure, mean percentage difference in wound area over 12 weeks, was 27% (96.9% vs. 69.9%; p=.003) in the per protocol analysis and 39.1% (90.24% vs. 51%; p<.001) in the intention-to-treat analysis. This treatment effect was also significant in the venous leg ulcer subgroup (p=.007). However, CIs were not reported. Confirmed wound closure (intention-to-treat) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted OR of 0.294 (95% CI, 0.135 to 0.638; p=.002) for all wound types and 0.398 (95% CI, 0.152 to 1.044; p=.061) for venous leg ulcer. The subgroup analysis for venous leg ulcer patients in the per protocol population was also not significant.

Smart Negative Pressure Wound Care System
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.[12,] Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.[13,] Approximately 70% of the study population had venous leg ulcers. Additional study details and limitations are summarized previously in indication 2.

A 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=.008).[19,] However, this study had a high loss to follow-up and lacked a comparison with standard treatment protocols.

Section Summary: Portable, Single-Use Therapy for Lower-Extremity Venous Ulcers
The evidence on portable, single-use NPWT for lower-extremity venous ulcers includes an RCT of the PICO device and an RCT of the nonpowered SNaP System. A 2019 RCT compared the PICO device with standard NPWT in outpatients with diabetic and venous ulcers. In this study, the PICO device demonstrated noninferiority for wound area reduction. No significant benefit in complete wound closure was found in patients with venous ulcers. One study of the SNaP System showed noninferiority to a V.A.C. device for wound size reduction. A subgroup analysis of this study found a significant difference in complete wound closure for patients with venous ulcers. However, interpretation of this study is limited by a high loss to follow-up and a lack of a control group treated with standard dressings. Well-designed comparative studies with larger numbers of patients powered to detect differences in complete wound closure are needed.

BURN WOUNDS

Clinical Context and Therapy Purpose
The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with burn wounds.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with burn wounds.

Interventions
The therapy being considered is outpatient NPWT, which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators
The following therapies are currently being used to make decisions about the treatment of burn wounds: standard wound care.

Outcomes
The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Follow-up at months to years is of interest to monitor relevant outcomes.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.
- Studies conducted exclusively in the inpatient setting were excluded.

REVIEW OF EVIDENCE

Randomized Controlled Trials

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.[20,] 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.[21,] 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.[22,]

Case Series

A retrospective case series by Ehrl et al (2017) examined outcomes for 51 patients treated for burned hands with topical NPWT 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.[23,]Before NPWT, patients received escharotomy or superficial debridement if needed, or split-thickness skin grafts for third-degree burns; the NPWT 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 1 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<.05). Despite a number of limitations, including heterogeneity of burned areas (2.5% to 70% throughout the series), the authors acknowledged NPWT 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 good 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 Therapy Purpose
The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with traumatic or surgical wounds.

The following PICO was used to select literature to inform this review.

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

Interventions
The therapy being considered is outpatient NPWT.

Comparators
The following therapies are currently being used to make decisions about the treatment of traumatic or surgical wounds: standard wound care.

Outcomes
The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Follow-up within weeks to months is of interest for outpatient NPWT to monitor relevant outcomes.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

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.
d. Studies with duplicative or overlapping populations were excluded.
e. Studies conducted exclusively in the inpatient setting 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.

REVIEW OF EVIDENCE

Systematic Reviews

Selected systematic reviews and meta-analyses evaluating the use of NPWT in surgical and/or traumatic wounds are summarized in Table 1.

Table 1. Summary of Systematic Reviews and Meta-Analyses of NPWT versus Standard Therapy in Surgical or Traumatic Wounds

Review	RCT	Other Studies	Participants[1]	N (Range)	Major Outcomes	Study Quality	Relevance
Cochrane (2022)[24,]	62	6	Individuals with postoperative wounds anticipated to heal by primary closure	13,340 (2 to 2035)	NPWT nonsignificantly reduced mortality and significantly reduced SSI	Unclear or high risk of bias noted	Studies generally included devices of interest; V.A.C. (n=7), PICO (n=20), PREVENA (n=24); however, outpatient use is often unspecified and may be limited
Li et al (2019)[25,]	45	0	Adult surgical patients	6624 (30 to 876)	SSIs were significantly lower; all other outcomes NSD	Certainty of the pooled effect ranked as low due to serious risk of bias	Studies generally included devices of interest; V.A.C. (n=12), PICO (n=11), PREVENA (n=15);

Review	RCT	Other Studies	Participants[1]	N (Range)	Major Outcomes	Study Quality	Relevance
							however, outpatient use is often unspecified and may be limited
De Vries et al (2016)[26,]	6	15	Individuals treated with prophylactic NPWT in clean and contaminated surgery	RCT: 277 (13 to 141) Other: 1099 (23 to 237)	Surgical site infection (RCT: p=.04; Other: p<.00001; NSD for trauma/orthopedic surgery)	Low quality of evidence due to lack of blinding in outcome assessment	Unclear; focus on inpatient therapy
Cochrane (2018)[27,]	7	0	Individuals with open traumatic wounds (open fractures and other types)	1377 (40 to 586)	Wound infection (NSD)	Unclear or high risk of bias noted	Limited; focus on inpatient therapy

NPWT: negative pressure wound therapy; NSD: no significant difference; RCT: randomized controlled trial; SSI: surgical site infection.
[1] Key eligibility criteria.

A 2022 Cochrane review update evaluated NPWT compared with standard dressings for surgical wound healing by primary closure.[24,] Negative pressure wound therapy was associated with a reduced risk of surgical site infection (SSI) (44 studies [N=11,403]; RR, 0.73; 95% CI, 0.63 to 0.85; I^2=29%). Mortality was lower with NPWT, but this was nonsignificant (11 studies [N=6384]; RR, 0.78; 95% CI, 0.47 to 1.30). No significant difference was found for wound dehiscence, reoperations, or wound-related readmission. The analysis is limited by inclusion of studies with mixed or unclear intervention types, no subgroup analysis for traditional or portable, single-use systems, and no discussion of use specific to outpatients.

A systematic review and meta-analysis by Li et al (2019) was conducted comparing the effectiveness and safety of NPWT with standard surgical dressing or conventional therapy for the prevention of SSI.[25,] A total of 45 RCTs assessing 6624 adult patients were included for analysis. Studies utilized a variety of NPWT devices, including V.A.C., PICO, and Prevena systems. Inclusion criteria did not impose restrictions on SSI grading systems or on surgery types. Surgeries for infected or chronic non-healing wounds including diabetic, venous, and arterial ulcers were excluded. Overall, NPWT was associated with a 40% reduction in SSI risk compared to control, with moderate heterogeneity (RR, 0.58; 95% CI, 0.49 to 0.69; I^2=19%; p<.00001). This significant reduction in risk was particularly maintained in high-risk surgical patients (32 RCTs; RR, 0.60; 95% CI, 0.50 to 0.73; I^2=23%; p<.00001). There was no significant effect of NPWT on wound dehiscence, hematoma occurrence, hospital admission, or length of hospital stay. The certainty of the evidence based on GRADE criteria was graded as low to very low due to the serious risk of bias stemming from lack of blinding and methodological flaws in SSI assessment and standardization. The authors suggest that further studies are warranted to elucidate the optimal protocol for NPWT utilization.

A systematic review and meta-analysis by De Vries et al (2016) included 6 RCTs and 15 observational studies of SSIs after prophylactic NPWT.[26,] One study selected used a portable device (PICO), 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 the use of NPWT reduced the rate of SSIs (OR, 0.56; 95% CI, 0.32 to 0.96; p=.04), and reduced the SSI rate from 140 to 83 per 1000 patients. However, the quality of evidence was rated as low due to the high risk of bias in the nonblinded assessments and imprecision in the estimates. Subgroup meta-analysis of 4 RCTs in orthopedic/trauma surgery did not demonstrate significant benefit in regards to reducing the risk of SSI (OR, 0.58; 95% CI, 0.32 to 1.07).

A 2018 Cochrane review evaluated the effects of NPWT for open traumatic wounds (eg, open fractures or soft tissue wounds) managed in any care setting.[27,] Seven RCTs were identified for the review with sample sizes ranging from 40 to 586 participants. Four studies (n=596) compared NPWT at 125 mmHg with standard care for open fracture wounds. Pooled data revealed no significant difference between groups in the number of participants with healed wounds (RR, 0.48; 95% CI, 0.81 to 1.27; I^2=56%). Pooled data from 2 studies (n=509) utilizing NPWT at 125 mmHg on other open traumatic wounds demonstrated no significant difference in risk of wound infection compared to standard care (RR, 0.61; 95% CI, 0.31 to 1.18). One study (n=463) assessing NPWT at 75 mmHg against standard care in other open traumatic wounds did not demonstrate a significant difference in wound infection risk (RR, 0.44; 95% CI, 0.17 to 1.10). One study comparing NPWT at 125 mmHg against 75 mmHg in other open traumatic wounds also failed to demonstrate a significant difference in wound infection risk (RR, 1.04; 95% CI, 0.31 to 3.51). Evidence was deemed low to very low in certainty and quality due to imprecision and risk of bias.

Randomized Controlled Trials

Selected RCTs of NPWT for surgical or traumatic wounds are summarized in Table 2.

Table 2. Summary of Key RCTs of NPWT versus Standard Therapy in Surgical Wounds

Study; Trial	Surgery Received	No. of Participants	Notes on NPWT effectiveness	P-value
Stannard (2012)[28,]	Various, after fractures and other trauma	249	Fewer infections, less discharge than standard closure	.049
Costa (2018); WOLLF[29,]	Severe open fracture of the lower limb	460	NSD in self-rated disability, number of deep SSI, or QOL scores	Disability:.13 SSI:.64 QOL: NR
Seidel (2020); SAWHI[30,]	Subcutaneous abdominal wound healing impairment	539 (randomized) 507 (modified intention-to-treat) 310 (per protocol)	Shorter time to wound closure and higher wound closure rate	<.001

NPWT: negative pressure wound therapy; NR: not reported; NSD: no significant difference; QOL: quality of life; RCT: randomized controlled trial; SAWHI: Subcutaneous Abdominal Wound Healing Impairment; SSI: surgical site infection; WOLLF: Effect of Negative Pressure Wound Therapy vs Standard Wound Management on 12-Month Disability Among Adults With Severe Open Fracture of the Lower Limb.

One of the larger studies on prophylactic NPWT for surgical wounds is a report from an investigator-initiated, industry-sponsored multicenter RCT of inpatient NPWT for closed surgical incisions by Stannard et al (2012).[28,] (A preliminary report was published in 2006.)[31,] 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 to 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=.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 QOL improvements compared with standard wound care.[32,]

The Effect of Negative Pressure Wound Therapy vs Standard Wound Management on 12-Month Disability Among Adults With Severe Open Fracture of the Lower Limb (WOLLF) trial by Costa et al (2018) randomized 460 patients with severe open fracture of the lower limb to NPWT (n=226) or standard wound management (n=234).[29,] The primary outcome was the Disability Rating Index score (range, 0 [no disability] to 100 [completely disabled]) at 12 months, with a minimal clinically important difference of 8 points. Secondary outcomes included deep infection and QOL measures based on the EuroQol 5-dimensions questionnaire. Eighty-eight percent of participants completed the trial. There were no statistically significant differences in disability scores (45.5 vs. 42.4; p=.13), in the number of deep infections (16 [7.1%] vs. 19 [8.1%]; p=.64), or in QOL measures in the NPWT and standard wound management groups, respectively. A 5-year follow-up report found similar patient-reported disability, health-related QOL, or need for surgery in patients treated with NPWT or standard management.[33,] NPWT was used for a limited time frame in the inpatient setting which limits conclusions for the outpatient setting.

The Subcutaneous Abdominal Wound Healing Impairment (SAWHI) multicenter clinical trial by Seidel et al (2020) randomized adult patients with SAWHI to treatment with NPWT (V.A.C. Therapy) or conventional wound therapy (CWT).[30,] The modified intention-to-treat population included 256 and 251 patients assigned to NPWT and CWT, respectively. The primary outcome, mean time to wound closure within 42 days, was significantly shorter in the NPWT group (difference, 3.0 d; 95% CI, 1.6 to 4.4; p<.001) and confirmed via independent, blinded assessors. Additionally, only 35.9% of patients in the NPWT group and 21.5% of patients in the CWT group achieved complete wound closure within 42 days (difference, 14.4%; 95% CI, 6.6% to 22.2%; p<.001). While this met the prespecified non-inferiority margin of 12.5%, the study's statistical model had assumed a complete wound closure rate of 50% in the CWT arm which had not been met within the 42-day treatment period. The benefit of NPWT for these outcomes was sustained in the per-protocol analysis, however, 39% and 31% of patients were excluded from the NPWT and CWT arms, respectively. Primary reasons for exclusion included unauthorized treatment crossovers, insufficient dressing changes, and treatment termination prior to 42 days. More wounds were sutured in the NPWT arm compared to the CWT arm, where more wounds

were healed by secondary intention. No significant differences were noted for QOL or pain measures at any time point. The RR for adverse events (RR, 1.20; 95% CI, 0.97 to 1.47) and wound-related adverse events (RR, 1.51; 95% CI, 0.99 to 2.35) was higher in the NPWT arm. The most frequently documented wound-related adverse events in the NPWT arm included periwound macerations and local infections with signs of inflammation. Overall, it is unclear if a 3-day difference in time to wound closure represents a clinically meaningful benefit. Time to hospital discharge, readmission rates, and duration of outpatient care were not reported; however, in an analysis of resource use, hospitalization time was longer with NPWT than CWT (11.8 days vs. 13.9 days).[34,] Time for dressing changes (196 vs. 278 minutes) and wound-related procedures (167 vs. 266 minutes) were significantly lower with NPWT.

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. Systematic reviews have generally found lower SSI with NPWT, but no significant difference in other outcomes. A systemic review in trauma wounds failed to find a significant difference in wound infections. Importantly, no systematic review has been specific to outpatient therapy, and it's unclear whether the results can be applied to this patient population. RCTs specific to outpatient NPWT in patients with traumatic or surgical wounds are lacking.

PORTABLE, SINGLE-USE THERAPY FOR TRAUMATIC AND SURGICAL WOUNDS

Clinical Context and Therapy 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 individuals with traumatic and surgical wounds.

The following PICO was used to select literature to inform this review.

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

Interventions
The therapy being considered is portable, single-use outpatient NPWT (powered or nonpowered), which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators
The following therapies are currently being used to make decisions about the treatment of traumatic or surgical wounds: treatment with standard, reusable NPWT devices or standard wound care.

Outcomes
The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Follow-up at weeks to months is of interest for portable, single-use outpatient NPWT to monitor relevant outcomes.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[2,]

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.
- Studies conducted exclusively in the inpatient setting were excluded.

REVIEW OF EVIDENCE

PICO Dressing

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 7 days, including the time after the hospital stay. Strengths of the trial included powered 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=.07) and postoperative surgical wound complications (8.4% control vs. 2.0% PICO, p=.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=.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.

Peterson et al (2021) reported on a single-site RCT evaluating the PICO system for incisional NPWT following cesarean delivery in women with class III obesity (body mass index ≥40; n=55) compared to standard dressings (n=55).[36,] An unplanned interim analysis was performed due to slow enrollment and publication of larger trials reporting no benefit for NPWT. The interim analysis demonstrated no significant difference in the primary composite outcome of wound complications between groups (risk difference, 9.1%; 95% CI, -8.3% to 25.8%; p=.38) and the trial was terminated early. A similarly designed trial evaluated the PICO system for incisional NPWT following cesarean delivery in women with risk factors for wound complications (diabetes, immunocompromise, chorioamnionitis, rheumatologic disease, history of wound complication, current anticoagulant therapy; n=79) compared to standard dressings (n=75).[37,]Patients were followed for up to 6 weeks after cesarean delivery. Results demonstrated that wound complication rates were similar between groups (19.4% vs. 19.7%, respectively; p=.43), as were wound infection rates (9% vs 7%, respectively; p=.70)

Prevena System
Pauser et al (2016) reported on a small RCT (n=21) evaluating Prevena in patients who had hemiarthroplasty for femoral neck fractures.[38,] Use of the Prevena System significantly reduced seroma size, days of wound secretion, wound care time, and need for dressing changes.

Murphy et al (2019) published findings from the Negative Pressure Wound Therapy Use to Decrease Surgical Nosocomial Events in Colorectal Resections (NEPTUNE) trial, a single-center, superiority-designed, prospective, randomized open-label trial evaluating the use of the Prevena System on closed incisions compared to standard gauze dressings in patients undergoing colorectal resection via laparotomy (N=300).[39,] There was no significant difference in the incidence of SSI at 30 days post-surgery between the Prevena and control groups (32% vs. 34%; p=.68). No significant difference in length of hospital stay was reported.

Hussamy et al (2019) reported on an open-label RCT evaluating the Prevena System for incisional NPWT following cesarean delivery in women with class III obesity (body mass index ≥40; n=222) compared to standard dressings (n=219).[40,] The overall composite wound morbidity rate was not significantly different between the Prevena and control cohorts (17% vs. 19%; RR, 0.9; 95% CI, 0.5 to 1.4).

Tuuli et al (2020) reported on a large, multicenter RCT evaluating the Prevena System for incisional NPWT following cesarean delivery in women with obesity (body mass index >30; n=806) compared to standard dressings (n=802).[41,] The risk of superficial or deep SSI was not significantly different between groups (difference, 0.36%; 95% CI, -1.46% to 2.19%; p=.70). The trial was terminated following a planned interim analysis which indicated an increased rate of adverse events in the Prevena group (difference, 6.95%; 95% CI, 1.86% to 12.03%; p<.001) and futility for the primary outcome.

Bertges et al (2021) conducted a multicenter RCT evaluating the Prevena System for groin incisions in patients undergoing infrainguinal revascularization (n=118) compared to standard dressing (n=124).[42,] The primary composite outcome of groin wound complications, SSI, major noninfectious wound complications, or graft infections within 30 days of surgery was not significantly different between Prevena and control groups (31% vs. 28%; p=.55).

Ceppa et al (2023) conducted a multicenter RCT evaluating the Prevena System (n=82) following major elective colorectal or hepatopancreatobiliary surgery compared to conventional wound therapy (n=82).[43,] The primary endpoint was the rate of postoperative incisional SSIs evaluated at inpatient day 4 or 5 and postoperative day 30; however, results were not stratified by SSI incidence at a specific time point (ie, inpatient vs outpatient occurrence). Results demonstrated that the overall occurrence of the primary endpoint did not significantly differ between the Prevena and conventional therapy groups (14% vs. 17%, respectively; p=.31).

Section Summary: Portable, Single-Use Therapy for Traumatic and Surgical Wounds
The evidence on portable single-use NPWT includes RCTs of the PICO device and RCTs 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 and 2 single-center RCTs of combined in- and outpatient use after cesarean delivery in women with obesity or other risk factors for poor wound healing. The evidence base for the Prevena System in the

outpatient setting is not sufficiently robust for conclusions on efficacy to be drawn. Well-designed comparative studies with larger numbers of patients treated in an outpatient setting are needed.

SUPPLEMENTAL INFORMATION
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

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 negative pressure wound therapy (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 input affirmed that therapeutic trials of NPWT for other acute or chronic wounds would not be medically necessary.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons
The American Academy of Orthopaedic Surgeons (AAOS) 2022 guidelines for prevention of surgical site infections after major extremity trauma included recommendations for NPWT.[44,] The recommendations from AAOS do not support the continued use of NPWT in patients undergoing fracture fixation due to similar outcomes to standard wound care but with an increased healthcare burden. In patients with high-risk surgical incisions, the AAOS recommends that limited evidence suggests NPWT may be an option; however, its use will be influenced by cost. Importantly, these guidelines do not specifically address use in the outpatient setting.

American College of Physicians
In 2015, the American College of Physicians published guidelines (now inactive) on the treatment of pressure ulcers.[45,] The guidelines stated there was low-quality evidence that the overall treatment effect of NPWT did not differ from the standard of care. Of note, the American College of Physicians considers these guidelines inactive since they are more than 5 years old.

Association for the Advancement of Wound Care
In 2010, the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of pressure ulcers. Negative pressure wound therapy 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.[46,]

In 2010, the AAWC published guidelines on the care of venous ulcers.[47,] The guidelines listed NPWT as a potential adjunctive therapy if conservative therapy does not work in 30 days. The guidelines noted there is limited evidence for NPWT (level B) compared with other adjunctive therapies.

International Multidisciplinary Consensus Recommendations
Willy et al (2017) presented evidence-based consensus guidelines on the use of closed incision negative pressure therapy (ciNPT) following surgery.[48,] 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 International Working Group on the Diabetic Foot
A 2023 guideline from the Society for the diagnosis and treatment of diabetic-related foot infections (DFIs) makes the following recommendation relevant to NPWT: "We suggest *not* using the following treatments to address DFIs: (a) adjunctive granulocyte colony-stimulating factor (G-CSF) treatment or (b) topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative-pressure wound therapy (with or without instillation)."[49,] This was graded as a conditional recommendation with low-quality evidence.

National Institute for Health and Care Excellence
In 2013, NICE issued guidance on NPWT for surgical wounds, concluding 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."[50,]

A 2015 NICE guidance on diabetic foot problems, updated in October 2019, has recommended consideration of NPWT after surgical debridement for diabetic foot ulcers on the advice of the multidisciplinary foot care service.[51,] 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 guidance on the prevention and management of pressure ulcers.[52,]The guidance stated, "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)." Also, the guidance did not recommend NPWT for neonates, infants, or children.

A 2019 NICE guidance recommends the use of the PICO7 negative pressure wound dressing for closed surgical incisions due to their association with fewer surgical site infections and seromas compared to standard wound dressings.[53,] The device is considered an option for those who are at high risk for surgical site infections, which may be driven by several factors (eg, age,

underlying illness, obesity, smoking, wound classification, and site and complexity of procedure). The device is recommended for those with low to moderate levels of wound exudate who will require infrequent dressing changes.

A 2021 NICE guidance on cesarean birth recommends considering the use of NPWT for women with a body mass index ≥35 kg/m^2 to reduce the risk of wound infections.[54,] Routine use of NPWT following cesarean delivery is not recommended. These recommendations were unchanged in a 2024 update to this guidance.

A 2021 NICE guidance states that while the V.A.C. Veraflo Therapy system shows promise in the treatment of acute infected or chronic non-healing wounds, there is not enough high-quality evidence to support the case for routine adoption.[55,] The guidance recommends research in the form of an RCT comparing the V.A.C. Veraflo Therapy system (NPWT with wound instillation) to NPWT alone.

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			
NCT05877378	Efficacy of PICO Single-use System in Chronic Ulcers	42	Apr 2024
NCT05389410	Comparison of Surgical Wound Healing and Complications Following Revision Hip and Knee Replacements, Utilising a 7-day Versus 14-day Negative Pressure Wound Therapy (NPWT) Dressing. A Randomised Controlled Trial	164	Feb 2027
NCT05064696	Prospective Comparison of Wound Complications After Anterior Total Ankle Arthroplasty With and Without PICO Negative Pressure Incisional Dressing	150	Sep 2025
NCT05071443	VACuum-Assisted Closure for Necrotizing Soft Tissue infecTIONs	130	Jun 2025
NCT05615844	A Randomized Controlled Trial Comparing Antibiotic Cement Bead Pouch Versus Negative Pressure Wound Therapy for the Management of Severe Open Tibia Fracture Wounds	312	Oct 2025
NCT03773575[a]	Evaluation of Closed Incision Negative Pressure Dressing (PREVENA) to Prevent Lower Extremity Amputation Wound Complications (PREVENA-AMP)	440	Aug 2024
NCT01913132	PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - A Prospective Randomized Trial	644	Dec 2025
NCT02813161	A Real World, Observational Registry of Diabetic Foot Ulcers and Quality of Care in Clinical Practice (DFUR)	10,000	Feb 2025

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT03414762	PICO Negative Pressure Wound Therapy in Obese Women Undergoing Elective Cesarean Delivery	153	Sep 2022
NCT04584957	Prophylactic Negative Pressure Wound Therapy in Gynecologic Oncology: a Prospective Controlled Randomized Trial (GO-VAC)	196	Sep 2021
NCT03948412	Negative Pressure Wound Therapy (PREVENA) Versus Standard Dressings for Incision Management After Renal Transplant (IMPART)	500	Sep 2021
NCT02509260	Prevena™ Incisional Negative Pressure Wound Therapy in Re-operative Colorectal Surgery	298	Feb 2021 (completed)
NCT01191567	Negative Pressure Wound Therapy. Therapy Effects and the Impact on the Patient's Quality of Life	200	Terminated
NCT02195310[a]	The Use of Prevena™ Incision Management System on Clean Closed Sternal Midline Incisions in Subjects at High Risk for Surgical Site Occurrences	342	Terminated

NCT: national clinical trial; NR: not reported.
[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. This may not be a comprehensive list of procedure codes applicable to this policy.

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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
97605	Negative pressure wound therapy (e.g., 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 (e.g., 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, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
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

REVISIONS	
August 3, 2006 with effective date of December 1, 2006	In "Policy" 1., 5th 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: • Added HCPCS code: A9272 (effective 1/1/2012).
	In the Reference section: • 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: ▪ 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)

REVISIONS	
04-30-2015	Updated Description section.
	In Policy section: ▪ 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: ▪ 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: ▪ Revised coding bullets.
	Updated References section.
02-15-2017	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Updated coding bullets.
	Updated References section.
06-23-2017	In Policy section: ▪ Added new Item D, "Non-electric vacuum assisted wound therapy (e.g., 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 (e.g., 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.
07-17-2020	Updated Description section
	Updated Rationale section.
	Updated References section
05-07-2021	Updated Description section

REVISIONS	
	In Policy Guidelines: • Added "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."
	Updated Rationale section.
	Updated References section.
03-08-2022	Updated Title to "Negative Pressure Wound Therapy in the Outpatient Setting"
	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed coding Bullets o The following HCPCS code was developed for a disposable NPWT system (e.g., the SNaP® or PICO™ systems): A9272. o 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. o There are 2 CPT codes for application of NWPT utilizing durable medical equipment: 97605, 97606. o The following HCPCS codes describe NWPT using an electrical pump: A6550, E2402. o There are also CPT codes for application of NPWT utilizing disposable, nondurable equipment: 97607, 97608.
	Updated References Section
02-28-2023	Updated Description Section
	Updated Rationale Section
	Updated References Section
03-26-2024	Updated Title to "Negative Pressure Wound Therapy"
	Updated Description Section

REVISIONS	
	Updated Policy Section ▪ Section A Removed: "in the home setting" and "when initiated in the home setting, or in the hospital or skilled nursing facility prior to discharge," A3: "Dehisced wounds or wounds with exposed hardware or bone, OR," A5: "Complications of a surgically created (i.e., large incisional hernia with mesh) or traumatic wound or" "where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment, OR," A6: "Post sternotomy wound infection or mediastinitis," A7: "It is used as an adjunct therapy or as an alternative to surgery; AND," and A8: "There is support to change the device and provide home care for the wound; AND" Added: "progressive wound healing has failed following 30 days of conservative wound treatment AND" ▪ Removed 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)." ▪ Added New Section B B. "Vacuum Assisted Wound Closure (VAC) is considered medically necessary in acute traumatic or post-surgical wounds, when ONE of the following acute wound conditions is present: 1. Dehisced wounds, OR 2. Wounds with exposed hardware or bone, OR 3. Foreign material within the wound, OR 4. Complications of a surgically created (i.e., large incisional hernia with mesh) or traumatic wound where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment, OR 5. Post sternotomy wound infection or mediastinitis" ▪ Removed Section G "Post-surgical VAC placement on new or acute wounds will be reviewed on a case by case basis."
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Diagnoses Box
	Updated References Section
02-25-2025	Updated Description Section
	Updated Rationale Section
	Updated Reference Section

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