Negative Pressure Wound Therapy in the Outpatient Setting

Effective: July 1, 2025

Next Review: December 2025
Last Review: March 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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

MEDICAL POLICY CRITERIA

I. A *1-month therapeutic trial* of a powered negative pressure wound therapy (NPWT) system (pump and supplies), may be considered **medically necessary** for one or more of the following:

   A. Open sternal wounds or repeat median sternotomy in high-risk obese patients; or

   B. Open abdominal wound including skin and subcutaneous tissue; or

   C. Open femoral wound including skin and subcutaneous tissue; or

   D. Sacral wounds; or

   E. Wounds with ileostomy or colostomy; or

   F. Necrotizing fasciitis; or

   G. Skin or other tissue grafts placed on an irregular surface/bed or compromised

blood flow, requiring initial placement of NPWT for graft fixation; or

H. Complex traumatic wounds including but not limited to those with degloving, substantial soft tissue defect, underlying fracture and/or hardware; or

I. Complex fistulous tract draining into a central wound; or

J. Wounds with high output drainage; or

K. For diabetic foot ulcers with wound classification of Wagner grade II or greater, all of the following (1. – 3.) must be met:

   1. A comprehensive diabetic management program; and
   2. Evaluation of arterial status; and
   3. Reduction in pressure on a foot ulcer with appropriate modalities.

L. For wounds when both of the following criteria (1. – 2.) are met:

   1. Documentation regarding conventional wound care is provided meeting all of the following criteria (a. – e.):
      a. Documentation in the medical record of evaluation, care, and wound measurements by a licensed medical professional; and
      b. Application of dressings to maintain a moist wound environment; and
      c. Debridement of necrotic tissue if present; and
      d. No documentation to suggested unaddressed inadequate nutritional status; and
      e. Documentation the open wound has not responded to conventional treatment after 30 days OR documentation of the decision-making process supporting less than 30 days of conventional treatment; and
   2. Any of the following wound-specific criteria are met:
      a. For Stage 3 or 4 pressure ulcers all of the following (i. – iii.) are met:
         i. Appropriate turning and positioning; and
         ii. Use of group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis; and
         iii. Moisture and incontinence have been appropriately managed; or
      b. For neuropathic (for example, diabetic) ulcers, all of the following (i. – iii.) must be met:
         i. A comprehensive diabetic management program; and
         ii. Evaluation of arterial status; and
         iii. Reduction in pressure on a foot ulcer with appropriate modalities; or
      c. For venous insufficiency ulcers, all of the following (i. – ii.) must be met:
         i. Compression bandages and/or garments applied consistently; and
         ii. Leg elevation and ambulation have been encouraged; or
      d. Chronic (at least 30 days) ulcer of mixed etiology.

II. Therapeutic trials of powered NPWT systems for the treatment of acute or chronic wounds are considered **not medically necessary** for any of the following:

A. Criterion I. is not met; or

B. One or more of the following contraindications are present:

1. The presence in the wound of necrotic tissue with eschar, if debridement is not attempted; or
2. Osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure; or
3. Cancer present in the wound; or
4. The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

III. Associated clinical care and supplies for the effective use of a NPWT system (e.g., wound care services; including for initiation and continuation of care) may be considered **medically necessary** if the primary NPWT system itself was determined to be medically necessary.

IV. Associated clinical care and supplies for the effective use of a NPWT system (e.g., wound care services; including for initiation and continuation of care) are considered **not medically necessary** if the primary NPWT system itself was determined to be not medically necessary or has not been reviewed for medical necessity.

V. *Continuation after a one-month therapeutic trial* of the powered NPWT system, as part of a comprehensive wound care program, may be considered **medically necessary** for up to 3 more months when both of the following criteria are met (A. – B.):

A. There is documentation that a licensed medical professional has directly assessed the wound(s) being treated with the NPWT system; and

B. There is continuous documentation of improvement (volume reduction, changes in dimensions and characteristics) which supports objective improvement in the wound.

VI. *Continuation after a one-month therapeutic trial* of the powered NPWT system is considered **not medically necessary** when any of the following occurs:

A. Criterion V. is not met; or

B. There is evidence of wound complications contraindicating continued use of NPWT.

VII. *Continuation after four total months* is considered **not medically necessary**.

VIII. Single-use/disposable NPWT systems (powered or nonpowered) and/or associated clinical care, supplies, and accessories are considered **investigational** for the treatment of acute or chronic wounds.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Wagner Grade Classification of Diabetic Foot Ulcers:[1]

Grade	Description
Grade 0	Skin intact but bony deformities lead to “foot at risk”
Grade 1	Superficial ulcer
Grade 2	Deeper; full thickness extension
Grade 3	Deep abscess formation or osteomyelitis
Grade 4	Partial Gangrene of forefoot
Grade 5	Extensive Gangrene

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

For *initial* one-month therapeutic trial:

1. History and physical/chart notes documenting policy criteria; and
2. Documentation, by provider, of indication for NPWT; and
3. Documentation of wound therapy program, including documentation of evaluation, care and wound measurements.

For *continuation* after a one-month therapeutic trial:

1. Documentation that a licensed medical professional has directly assessed the wound(s) being treated with the NPWT system; and
2. There is continuous documentation of improvement (volume reduction, changes in dimensions and characteristics) which supports objective improvement in the wound.

In addition, for neuropathic (e.g., diabetic) ulcers:

1. Documentation of arterial status, for example, ankle brachial index (ABI) and/or toe plethysmography.

CROSS REFERENCES

1. Electrical Stimulation for the Treatment of Wounds, Durable Medical Equipment, Policy No. 83.09
2. Non-Contact Ultrasound Treatments for Wounds, Medicine, Policy No. 131

BACKGROUND

CHRONIC WOUNDS

Management

The management and treatment of chronic wounds, including decubitus ulcers, is challenging.

Most chronic wounds will heal only if the underlying cause (ie, venous stasis, pressure, infection) is addressed. Also, cleaning the wound to remove 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; 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 (Spiracur, acquired by Acelity in 2015), is a class II device requiring notification to market but not having the FDA premarket approval. In 2009, it was cleared for marketing by the FDA 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.

NPWT devices with instillation include the V.A.C. VERAFLO™ Therapy device (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.[2]

FDA product code: OMP.

EVIDENCE SUMMARY

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

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

This review was informed by a 2000 TEC Assessment that evaluated negative pressure therapy of pressure ulcers, venous ulcers, and diabetic ulcers.[3] Literature updates for this review have focused on comparative trials with the features described in the 2000 TEC Assessment (e.g., 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 NPWT for the healing of acute wounds.

NPWT devices are classified as either powered (i.e., requiring an electrical power source or batteries) or nonpowered (mechanical). Most evidence found in the literature is for electrically powered devices with large canisters (e.g., 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:[4]

- 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

SYSTEMATIC REVIEWS

The authors of a systematic review for the Agency for Healthcare Research and Quality and the Centers for Medicare & Medicaid Services (2014) reported that due to insufficient evidence, they were unable to draw conclusions about the efficacy or safety of NPWT in the home setting.[5] There were three retrospective cohort studies on diabetic foot ulcers and arterial ulcers, an RCT and two retrospective cohort studies on pressure ulcers, and a retrospective cohort on venous ulcers. Six studies used the V.A.C., and the other used the Smart Negative Pressure (SNaP) Wound Care System device. Reviewers found that interpretation of available data was limited by variability in the types of comparator groups, methodologic limitations, and poor reporting of outcomes.[6]

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.[7]

A 2020 Cochrane review update by Norman evaluated NPWT compared with standard dressings for surgical wound healing by primary closure.[8] Forty-four RCTs were included for analysis (n=7,447). NPWT was associated with a reduced risk of surgical site infection (SSI) (31 studies [n=6,204]; RR 0.66; 95% CI, 0.55 to 0.80; I^2=23%). However, subgroup analysis by surgery type did not maintain a significant benefit for orthopedic, abdominal, or mixed/general surgeries. Treatment benefit for SSI was significant in clean and clean-contaminated procedures only. No significant difference was found for the rates of mortality and wound dehiscence. No significant benefit was seen for rates of reoperations or hospital readmissions. Certainty of evidence was deemed low to moderate per GRADE criteria. Studies were generally limited by imprecision and unclear or high-risk of bias in allocation concealment and blinding of outcome assessors. The analysis was also limited by inclusion of studies with mixed or unclear intervention types and no subgroup analysis for traditional or portable, single-use systems. An update to this above-mentioned systematic review was published by Norman in 2022 to assess the effects of NPWT for preventing SSI in wounds healing through primary closure.[9] In this update to their existing systematic review series, the authors added 18 new randomized controlled trials (RCTs) and one new economic study, resulting in a total of 62 RCTs (13,340 included participants) and six economic studies. Studies evaluated NPWT in a wide range of surgeries, including orthopaedic, obstetric, vascular and general procedures. All studies compared NPWT with standard dressings. This review also confirmed that the use of NPWT could reduce the risk of SSI in wound healing compared to the standard dressing group. But there is probably little or no difference in wound dehiscence between people treated with NPWT and those treated with standard dressing.

A systematic review and meta-analysis by Li (2019) was conducted comparing the effectiveness and safety of NPWT with standard surgical dressing or conventional therapy for prevention of SSI.[10] A total of 45 RCTs assessing 6,624 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<0.00001). 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<0.00001). 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 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.

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 patients with diabetic lower-extremity ulcers or amputation wounds.

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 systematic review and meta-analysis by Chen (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<0.001) based on six RCTs representing 536 patients.[11] No significant difference in the incidence of adverse events was reported between groups (OR, 0.49; 95% CI, 0.10 to 2.42; p=0.38). The reviewers noted several limitations in the body of evidence, including lack of blinding, unclear follow-up durations, and heterogeneous pressure settings.

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.[12] 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 2013 Cochrane review of NPWT for treating foot wounds in patients with diabetes[13] was updated in 2018 to include 11 RCTs (n=972) with sample sizes ranging from 15 to 341 participants.[14] Two studies addressed post-amputation wounds and all other studies described treatment of diabetic foot ulcers. Only one 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 (RR 1.44, 95% 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 1.91, 95% CI, 1.21 to 2.99) compared with moist dressings. Data from three 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, I2=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.

Randomized Controlled Trials

Seidel (2020) reported the results of a multicenter, industry-sponsored, blinded RCT that evaluated the superiority of NPWT (n=171) compared to standard moist wound care (n=174) in patients with diabetic foot ulcers.[15] The NPWT devices used included V.I.A. and Renasys systems. Based on intention-to-treat analysis, the primary outcomes of complete, sustained, and confirmed wound closure or time to wound closure, as defined by 100% epithelialization, no drainage, no suture material, and no need for wound dressing or adjuvants within 16 weeks, was not significantly different between NPWT and control groups (p=.53 and p=.100, respectively). The incidence of adverse events was significantly higher in the NPWT arm (56.1%) compared to the control arm (41.4%; p=0.007); however, only 16 adverse events were considered related to NPWT. Amputation rates were not significantly different between groups (difference, 0.2%; 95% CI, -19.0% to 18.6%; p=1.00). Limitations include a high number of patients (n=191) with missing data or protocol deviations.

Associated to the study mentioned above, Seidel (2022) published another RCT to compare resource utilization of NPWT and standard moist wound care (SMWC) for diabetic foot wounds after amputation, surgical debridement or wound cleansing.[16] Treatment duration was 16 days shorter with NPWT (mean (SD) 82.8 (31.6), SMWC 98.8 (24.6); U test, p = 0.001) with 14.9 days shorter outpatient treatment (mean (SD) NPWT 68.3 (31.1), SMWC 83.2 (29.7)). The number of dressing changes per study participant was lower with NPWT (mean (SD) 35.1 (18.6), SMWC (42.9 (21.4); U test, p = 0.067). Time per dressing change was significantly lower with SMWC (mean (SD) 19.7 (12.8), NPWT (16.5 (8.2) minutes; U test, p<0.0001). Time for surgical debridements per study participant was 23.3 minutes shorter with NPWT (mean (SD) 20.5 (20.5), SMWC (43.8 (46.7); U test, p = 0.395).

The largest study of NPWT for diabetic foot ulcers was a multicenter industry-sponsored RCT by Blume (2008) that compared NPWT with advanced moist wound therapy.[17] Included were

342 patients with Wagner grade 2 or grade 3 foot ulcers of at least 2 cm^2; the chronicity of the ulcers was not described. Based on intention-to-treat analysis, a greater proportion of NPWT-treated foot ulcers achieved the primary endpoint of complete ulcer closure (43.2% vs. 28.9%, p=0.007) within the 112-day active treatment phase. For the 240 (72%) patients who completed the active treatment phase, 60.8% of NPWT-treated ulcers closed compared with 40.0% of ulcers treated with advanced moist wound therapy. NPWT patients also experienced significantly fewer secondary amputations (4.1% vs. 10.2%, p=0.035).

Nonrandomized Studies

Borys (2018) conducted a prospective observational study to assess the short-term efficacy, safety, and long-term outcomes of NPWT in treating diabetic foot ulcers. Researchers assigned 75 patients to NPWT (n=53) or standard care (n=22) based on wound size. Analysis after one-year follow-up showed similar results for both groups, leading researchers to conclude NPWT is a safe alternative to but not necessarily more efficacious than the current standard of care. Limitations include small sample size, the observational design, and non-consideration of risk factors other than wound size.[18]

Section Summary: Diabetic Lower-Extremity Ulcers and Amputation Wounds

The evidence on NPWT for diabetic lower-extremity ulcers and amputation wounds includes RCTs and 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 patients with diabetic lower-extremity ulcers or amputation wounds.

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 two sterile dressings and has a lifespan of 7 to 14 days.

Kirsner (2019) published an RCT that allocated 164 patients with venous leg ulcers (VLU; n=104) or diabetic foot ulcers (DFU; n=60) to treatment with PICO single-use NPWT (s-NPWT; n=80) or traditional, reusable NPWT systems (t-NPWT; n=84).[19] Prior to randomization, patients were excluded if a reduction in target ulcer area greater than or equal to 30% was achieved with compression or offloading during a two 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 (ITT) analysis. For the per protocol (PP) 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; SD, 23.4 mmHg) applied.

The study intended to test for noninferiority in the percentage change of target ulcer area with s-NPWT vs t-NPWT over the course of a 12-week treatment period, with a noninferiority margin of 12.5%. The analysis was performed with the PP population to account for dropouts and then repeated on the full analysis set (ITT). 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=0.003) in the PP analysis and 39.1% (90.24% vs 51%; p<0.001) in the ITT analysis. This treatment effect was also significant in the DFU subgroup (p=0.031). However, confidence intervals were not reported for the primary outcome.

Confirmed wound closure (ITT) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted odds ratio of 0.294 (95% CI, 0.135 to 0.638; p=0.002) for all wound types and 0.161 (95% CI, 0.035 to 0.744; p=0.020) for DFU. However, the subgroup analysis for DFU patients in the PP 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 quality of life 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 three treated with s-NPWT and nine 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 DFU.

Kirsner (2021) published a subanalysis of this RCT highlighting outcomes in patients with lower-extremity (foot and venous leg) diabetic ulcers.[20] 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<0.001). 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=0.017). 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.

SNaP Wound Care System

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

Armstrong (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.[21] Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.[22] The trial enrolled 132 patients with lower-extremity venous or diabetic ulcers with a surface area between 1 cm2 and 100 cm2 and diameter less than 10 cm present for more than 30 days despite appropriate care. Approximately 30% of patients in this study had diabetic ulcers, and no subgroup analyses were conducted. Dressings were changed per the manufacturer's direction: two times per week in the SNaP group and three times per week in the V.A.C. group. Patients were assessed for up to 16 weeks or until complete wound closure; 83 (63%) patients completed the study. Intention-to-treat analysis with the last observation carried forward showed noninferiority in the primary outcome of wound size reduction at 4, 8, 12, and 16 weeks. When adjusted for differences in wound size at baseline, SNaP-treated subjects showed noninferiority to V.A.C.-treated subjects at 4, 12, and 16 weeks. Kaplan-Meier analysis showed no significant difference in complete wound closure between the two groups. At the final follow-up, 65.6% of the V.A.C. group and 63.6% of the SNaP group had wound closure. Survey data indicated that dressing changes required less time with the SNaP device and use of the SNaP device interfered less with mobility and activity than the V.A.C. device.

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.[23] 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 patients with chronic pressure ulcers.

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

Shi (2023) published an update to the 2015 Cochrane review on treating pressure ulcers in any care setting.[24] The review included eight RCTs with 327 participants total. Six of the eight included studies were deemed to be at a high risk of bias in one or more risk of bias domains, and evidence for all outcomes of interest was deemed to be of very low certainty. Most studies had small sample sizes (range: 12 to 96, median: 37 participants). Five studies compared NPWT to dressings, but only one study reported outcomes that met the review criteria (complete wound healing and adverse events). This study had only 12 participants and there were very few events; only one participant was healed in the study (risk ratio [RR] 3.00, 95% confidence interval [CI] 0.15 to 61.74, very low-certainly evidence). No difference in adverse events was reported, but the evidence for this outcome was also assessed as very low certainty (RR 1.25, 95% CI 0.64 to 2.44). The authors concluded that the efficacy, safety, and

acceptability of NPWT in treating pressure ulcers compared to usual care are uncertain due to the lack of key data on complete wound healing, adverse events, time to complete healing, and cost-effectiveness.

A 2015 Cochrane review included four RCTs of NPWT (total n=149 patients) for treating pressure ulcers in any care setting, although most of the patients were treated in a hospital setting.[13] Three trials were considered to be at high-risk of bias, and all evidence was considered to be of very low-quality. Only one 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.

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.[25] 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 patients with lower-extremity ulcers due to venous insufficiency.

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.[26] This trial, published by Vuerstaek (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 six months in duration.[27] Full-thickness punch skin grafts from the thigh were applied, followed by four days of NPWT or conventional care to assure complete graft adherence. Each group then received standard care with nonadhesive dressings and compression therapy until complete healing (primary outcome) occurred. The median time to complete healing was 29 days in the NPWT group and 45 days in the control group (p=0.001). Ninety percent of ulcers treated with NPWT healed within 43 days, compared with 48% in the control group. These results would suggest that NPWT significantly hastened wound healing, although the use of skin autografts makes it difficult to discern the contribution of NPWT to the primary outcome. The 2015 Cochrane review did not identify any RCT evidence on the effectiveness of NPWT as a primary treatment for leg ulcers, nor was there any evidence on the use of NPWT in the home setting.

Section Summary: Lower-Extremity Ulcers due to Venous Insufficiency

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

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 patients with lower-extremity ulcers due to venous insufficiency.

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 (2019) published an RCT that allocated 164 patients with venous leg ulcers (VLU; n=104) or diabetic foot ulcers (DFU; n=60) to treatment with PICO single-use NPWT (s-NPWT; n=80) or traditional, reusable NPWT systems (t-NPWT; n=84).[19] Additional study details and limitations are summarized previously in the policy section on portable, single-use therapy for diabetic lower-extremity ulcers and amputation wounds.

The primary outcome measure, mean percentage difference in wound area over 12 weeks, was 27% (96.9% vs 69.9%; p=0.003) in the per protocol (PP) analysis and 39.1% (90.24% vs 51%; p<0.001) in the intention-to-treat (ITT) analysis. This treatment effect was also significant in the VLU subgroup (p=0.007). However, confidence intervals were not reported. Confirmed wound closure (ITT) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted odds ratio of 0.294 (95% CI, 0.135 to 0.638; p=0.002) for all wound types and 0.398 (95% CI, 0.152 to 1.044; p=0.061) for VLU. The subgroup analysis for VLU patients in the PP population was also not significant.

SNaP Wound Care System

Armstrong (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.[21] Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.[22] Approximately 70% of the study population had venous leg ulcers. Additional study details and limitations are summarized previously in indication 2.

Marston (2015) published a subgroup analysis of 40 patients with venous leg ulcers who completed the study showed a significant improvement in the percentage of those with complete wound closure treated with SNaP (57.9%) compared with the V.A.C. system (38.2%; p=0.008).[28] 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 patients with burn wounds.

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.[29] 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 (2012) on the effect of NPWT on graft take in full-thickness burn wounds.[30] This multicenter, four-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 four to seven 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.[31]

Case Series

A retrospective case series by Ehrl (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.[32] Before NPWT, patients received escharotomy or superficial debridement if needed, or split-thickness skin grafts for third-degree burns and 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 one or both outcomes: the first endpoint was reached in 85.1% (n=40) of the cases; the second endpoint was reached in 78.7% of hands (n=37). When evaluated using the Disabilities of the Arm, Shoulder, and Hand questionnaire (scoring range, 0-100; with 0=no disability), patients with injuries resulting in hypertrophic scarring had significantly worse scores (28.8) than patients without similar scarring (11.7; $p<0.05$). Despite a number of

limitations, including heterogeneity of burned areas (2.5% to 70% throughout the series), the authors acknowledged 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 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 patients with traumatic or surgical wounds.

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.

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 SR-MAs of NPWT versus Standard Therapy in Surgical Wounds

Review	RCT	Other Studies	Participants[1]	N (Range)	Major Outcomes	Study Quality	Relevance
Cochrane (2014)[33]	9	0	Individuals with wounds expected to heal by primary	785	SSI (NSD) Wound dehiscence (NSD)	Unclear or high risk of bias noted	Unclear; inclusion of "home-made"

Review	RCT	Other Studies	Participants[1]	N (Range)	Major Outcomes	Study Quality	Relevance
			intention (eg, surgical closure, skin grafts)		Reoperation (NSD) Seroma/hematoma (NSD) Skin graft failure (NSD)		devices and focus on inpatient therapy
De Vries (2016)[34]	6	15	Individuals treated with prophylactic NPWT in clean and contaminated surgery	RCT: 277 (13-141) Other: 1099 (23-237)	Surgical site infection (RCT: p=0.04; Other: p<0.00001; NSD for trauma/orthopedic surgery)	Low quality of evidence due to lack of blinding in outcome assessment	Unclear; focus on inpatient therapy
Cochrane (2018)[14]	7	0	Individuals with open traumatic wounds (open fractures and other types)	1377 (40-586)	Wound infection (NSD)	Unclear or high risk of bias noted	Limited; focus on inpatient therapy
Ren (2022)[35]	5	1 (retrospect-tive cohort trial)	Individuals who have undergone hepatopan-creatobiliary surgery	657 (345F, 311M)	superficial surgical infection, deep surgical infection, seroma incidence, hematoma incidence, and hospital re-admission		

NPWT: negative pressure wound therapy; NSD: no significant difference; RCT: randomized controlled trial; SR-MA: systematic review and meta-analysis; SSI: surgical site infection.
1 Key eligibility criteria,
2 Assessment according to Cochrane risk of bias criteria.

A 2014 Cochrane review evaluated the evidence on NPWT for skin grafts and surgical wounds expected to heal by primary intention.[33] Healing by primary intention occurs when the wound edges are brought together with sutures, staples, tape, or glue, and contrasts with healing by secondary intention, where the wound is left open to heal from the bottom up (eg, for chronic or infected wounds). Nine randomized trials (total n=785 patients) were included in the review. Three trials involved skin graft patients, four included orthopedic patients, and two included general surgery and trauma surgery patients. All trials had an unclear or high-risk of bias. There were no differences between standard dressing and NPWT for SSIs, wound dehiscence, reoperation (in incisional wounds), seroma/hematoma, or failed skin grafts. Pain intensity was reported to be lower with “home-made” NPWT compared with commercial devices. Most or all studies appeared to have used short-term application of NPWT in an inpatient setting.

A systematic review and meta-analysis by De Vries (2016) included 6 RCTs and 15 observational studies of SSIs after prophylactic NPWT.[34] One study selected used a portable device (PICO, described below), while the others used a V.A.C. Unlike the 2014 Cochrane review, studies on skin grafts were not included. Meta-analysis of the RCTs showed that use of NPWT reduced the rate of SSIs (odds ratio [OR], 0.56; 95% CI, 0.32 to 0.96; p=0.04), and reduced the SSI rate from 140 to 83 per 1000 patients. However, the quality of evidence was rated as low due to high-risk of bias in the nonblinded assessments and imprecision in the estimates. Subgroup meta-analysis of four RCTs in orthopedic/trauma surgery did not demonstrate significant benefit in regards to reducing 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.[14] 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 two 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 for 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.

In contrast, a systematic review and meta-analysis by Liu (2018) highlighted a significantly lower infection rate, shorter wound coverage time, shorter wound healing time, and shorter hospitalization duration for NPWT versus conventional wound dressings in the treatment of open fractures (all p<0.00001).[36] Three of six included RCTs overlapped with the Cochrane review and one significantly weighted RCT (n=460) (see Costa [2018][37] in Table 2 below) failing to demonstrate a benefit in infection risk for NPWT was missing in the Liu (2018) analysis, the only RCT identified by Cochrane to conduct blinded outcome assessment of wound healing and infection. However, the risk of bias in the Liu (2018) review was similarly reported as high or unclear. The baseline characteristics of cohort studies included in the analysis suffered from high heterogeneity, with most studies failing to achieve comparable initial injury severity scores based on the Gustilo-Anderson open fracture classification system. Finally, due to the severity of open fracture injuries, the outpatient clinical utility of NPWT for this form of trauma is unclear with most studies focusing on inpatient applications.

Sahebally (2018) performed a systematic review with meta-analysis to evaluate the effects of NPWT on SSIs in closed laparotomy incisions.[38] Researchers searched four databases through December 31, 2017, and screened bibliographies of retrieved studies to find further studies; nine unique studies (three RCTs, two prospective studies, and four retrospective studies) representing 1,266 unique patients were included in the review. The analysis determined that NPWT was associated with a significantly lower rate of SSI compared with standard wound dressing (pooled OR: 0.25; 95% CI 0.12 to 0.52; p<0.001). The review was limited by including mostly non-randomized studies and use of different NPWT devices.

Flynn (2020) published an RCT to determine if PICO dressings reduce surgical site infections or other surgical site complications in primarily closed laparotomy incisions after clean-contaminated surgery in moderate-risk patients.[39] Patients undergoing laparotomy and bowel resection were randomly assigned to PICO or conventional dressings. There were no significant differences in the surgical site infection or development of surgical site complications between the two techniques. The authors conclude that this study does not support the routine use of PICO dressings on uncomplicated laparotomy incisions in moderate-risk patients.

Ren (2022) performed a systematic review to evaluate the comparative influence of NPWT and standard surgical dressing administration on incidence risk for surgical site infections, complications, and hospital re-admission after hepatopancreatobiliary surgery.[35] Six studies were included in this analysis; five RCTs and one retrospective cohort trial. From this study the authors report that NPWT usage slightly reduces the risk of hospital readmission as compared to standard surgical dressing. Only two studies (featuring small sample sizes) investigated the comparative impact of NPWT and standard surgical dressing on hematoma complications.

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)[40]	Various, after fractures and other trauma	249	Fewer infections, less discharge than standard closure	0.049
Masden (2012)[41]	Various	81	NSD in infection or healing	NR
Chio and Agrawal (2010)[42]	Radial forearm donor site	43	NSD in wound complications or graft failure	NR
Javed (2018)[43]	Open pancreaticoduodenectomy	123	9.7% of NPWT group developed infections, compared with 31.1% of standard closure group	0.003
Tanaydin (2018)[44]	Bilateral breast reduction mammoplasty	32	Patients used as own control; NPWT associated with significantly lower risk of complication and improved pain and scarring compared with fixation strips	<0.004
Costa (2018); WOLLF[37]	Severe open fracture of the lower limb	460	NSD in self-rated disability, number of deep SSI, or QOL scores	Disability: 0.13 SSI: 0.64 QOL: NR
Seidel (2020); SAWHI[45]	Subcutaneous abdominal wound healing impairment	539 (randomized) 507 (modified ITT) 310 (PP)	Shorter time to wound closure and higher wound closure rate	<0.001

ITT: intention-to-treat; NPWT: negative pressure wound therapy; NR: not reported; NSD: no significant difference; QOL: quality of life; PP: per protocol; RCT: randomized controlled trial; SSI: surgical site infection.

One of the largest 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 (2012).[40] (A preliminary report was published in 2006.)[46] 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=0.049). Wound dehiscence after discharge was observed less frequently in the NPWT group (8.6%) than in the control group (16.5%). These results would support the efficacy of the short-term use of NPWT when used under highly controlled conditions of inpatient care, but not the effectiveness of NPWT in the outpatient setting. A small 2015 RCT (n=20) of NPWT in an outpatient setting reported that patients treated with NPWT required significantly fewer dressing changes, reported significantly less pain, and experienced quality of life improvements compared with standard wound care.[47]

Other randomized studies have reported no benefit for NPWT for surgical wounds, as reflected in the conclusions of various Cochrane reviews (described above).[14, 33] For example, the RCT by Masden (2012) examined the use of NPWT for surgical closures at high-risk for nonhealing in 81 patients with comorbidities that included diabetes and peripheral vascular disease.[41] At a mean of 113 days follow-up, there were no significant differences in the proportions of patients with wound infection, time to develop infection or dehiscence between NPWT and dry dressing groups. Chio and Agrawal (2010) published results of a randomized trial of 54 patients comparing NPWT with a static pressure dressing for the healing of the radial forearm free flap donor site.[42] There were no statistically significant differences in wound complications or graft failure (percentage of area for graft failure, 7.2% for negative pressure vs 4.5% for standard dressing). Biter (2014) found no significant advantage of two weeks of NPWT in 49 patients who underwent surgical excision for pilonidal sinus disease.[48] Complete wound healing was achieved at a median of 84 days in the NPWT group and 93 days in controls.

Javed (2018) conducted a single-site RCT to evaluate the efficacy of NPWT for SSI after an open pancreaticoduodenectomy. Researchers randomized 123 patients treated from January 2017 through February 2018 to either NPWT (n=62) or standard closure (n=61). In the study, 9.7% of patients who received NPWT developed a postoperative infection at the site, compared with 31.1% of patients who received standard closure, an RR of 0.31 (95% CI 0.13 to 0.73; p=0.003). Limitations of the study included being conducted at a high-volume treatment center and a lack of blinding.[43]

Tanaydin (2018) conducted an RCT to compare NPWT to standard wound care after a bilateral breast reduction mammoplasty.[44] In the study, 32 patients were given NPWT on one breast and fixation strips on the other, simultaneously serving as study group and control group. Sites treated with NPWT showed a significantly lower rate of complications (p<0.004) compared to fixation strips, as well as improved pain and scarring. Limitations included the small sample size and lack of blinding.

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 (2018) randomized 460 patients with severe open fracture of the lower limb to NPWT

(n=226) or standard wound management (n=234).[37] 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 quality of life 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=0.13), in the number of deep infections (16 [7.1%] vs. 19 [8.1%]; p=0.64), or in quality of life measures in the NPWT and standard wound management groups, respectively. A five-year follow-up report found similar patient-reported disability, health-related quality of life, or need for surgery in patients treated with NPWT or standard management.[49] 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 (2020) randomized adult patients with SAWHI to treatment with NPWT (V.A.C. Therapy) or conventional wound therapy (CWT).[45] The modified ITT 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<0.001) 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<0.001). 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 PP 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 healed by secondary intention. No significant differences were noted for quality of life or pain measures at any time point. The relative risk 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.

As an add-on to a multicenter randomized clinical trial, Seidel (2022) published another RCT.[50] The authors compared aspects of hospital discharge, outpatient treatment continuation, and subsequent wound closure outcomes between the treatment arms in patients with subcutaneous abdominal wound healing impairment after surgery without fascia dehiscence in the per protocol population. Time to wound closure was shorter for outpatients in the NPWT arm (outpatient transfer with: NPWT Mean ± standard error 28.8 ± 8.0 days; CWT 28.9 ± 9.5 days) than in the conventional treatment arm (30.4 ± 8.0 days). The authors also report that study site specific avoidance of outpatient NPWT emerges as an additional reason for the prolonged hospitalization time.

Seidel (2022) also published the comparison of resource utilization of NPWT and CWT for SAWHI after surgery.[51] The resource use analysis was primarily based on the per protocol population (NPWT 157; CWT 174). Although treatment length within 42 days was significantly shorter in the NPWT arm (Mean [Standard deviation (SD)] NPWT 22.8 (13.4); CWT 30.6 (13.3); p<0.001 U-test), hospitalization time was shorter with CWT [Mean (SD) NPWT 13.9

(11.1); CWT 11.8 (10.8); p=0.047 U-test]. Significantly more study participants were outpatient with CWT [n=167 (96.0%)] than with NPWT [n=140 (89.2%) (p=0.017)]. Time for dressing changes per study participant [Mean (SD) (min) NPWT n=133, 196 (221.1); CWT n=152, 278 (208.2); p<0.001 U-test] and for wound-related procedures [Mean (SD) (min) NPWT 167 (195); CWT 266 (313); p<0.001 U-test] was 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. One RCT found no benefit of NPWT on graft take and wound epithelialization in patients with full-thickness burns. Another RCT found a significant decrease in time to wound closure in patients with wound healing impairment following abdominal surgery; however, it is unclear if this difference is clinically meaningful. An RCT reported significantly shorter treatment length within NPWT compared to the conventional wound healing. In addition, it also reported shorter hospitalization time, significantly more outpatients, and significantly lesser time for dressing. Another RCT also reported shorter time to wound closure and it was noted that study site specific avoidance of outpatient NPWT emerges as an additional reason for the prolonged hospitalization time. A small RCT suggested that prophylactic NPWT might reduce the number of dressing changes and pain when used in an outpatient setting. A small retrospective study reported improved epithelialization in patients free of comorbidities treated with NPWT. In other studies, NPWT showed no benefit for the treatment of patients with surgical wounds or skin grafts healing by primary intention, and a systematic review of NPWT for traumatic and surgical wounds found no differences between standard dressing and NPWT for any wound outcome measure. Another systematic review reported that NPWT was associated with lower rate of surgical site infections. Yet another systematic review reported that NPWT usage slightly reduces the risk of hospital readmission as compared to standard surgical dressing. Additional study in a larger, outpatient sample may be needed to evaluate this outcome measure.

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 patients with traumatic and surgical wounds.

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 two sterile dressings and has a lifespan of 7 to 14 days. Karlakki (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.[52] The device was left on for seven 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=0.07) and postoperative surgical wound complications (8.4% control vs. 2.0% PICO, p=0.06). However, most of the difference in length of stay was due to wound complications in two outliers in the control group (up to 61 days). The level of wound exudate was significantly reduced by the PICO device (p=0.007), with 4% of the study group and 16% of the control group having grade 4 (scale grade, 0 to 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.

Imcha (2023) published a retrospective, observational study of the PICO system among 1,111 high-risk patients undergoing cesarean section across eight hospitals.[53] Risk factors included a BMI of 30 or higher, smoking, diabetes, and whether the patients had undergone previous C-sections or had a previous history of wound dehiscence. Outcomes were compared to historical controls treated with standard dressings. Of the 1,111 patients, 106 (9.5%) developed surgical site complications, mostly superficial surgical site infections (78 of 106; 73.6%). Second most common was wound dehiscence (25 of 106; 23.6%), followed by deep surgical site infection (8 of 106; 7.5%) Reductions in the incidence of surgical site complications were reported across BMI groups: 18.5 to 24.9 (6.7% to 2.3%, p=0.02), 25 to 29.9 (9.6% to 3.5%, p=0.003), and 35 or higher (19.3% to 14.2%, p=0.04). There was no significant difference in surgical site complications for BMI 30 to 34.9 (13.5% to 8.9%; p=0.12) This study is limited by retrospective design, use of historical data for controls, and self-reported complications. In addition, while this study included only high-risk patients, historical controls included all patients. There were also significant protocol variations between the current data and historical controls including different definitions of wound dehiscence and the assumption that all dehiscence events occurred with infection.

Peterson (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).[54] 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=0.38) and the trial was terminated early. In the systematic review by Norman (2022) an RCT by Hyldig (2020) evaluated the cosmetic result of using incisional negative-pressure wound therapy (iNPWT) compared with standard postsurgical dressings in obese women undergoing cesarean delivery.[9] The authors report that this study was not able to detect a difference in the long-term cosmetic result after cesarean delivery when compared with standard dressings. On the other hand, a few other RCTs in this systematic reviews demonstrated a reduction of surgical site infections by prophylactic incisional negative

pressure wound therapy compared with standard postoperative dressings in obese women giving birth by cesarean section. The effect remained statistically significant when adjusted for BMI and other potential risk factors. Another systematic review and meta-analysis by Gillespie (2022) also looked at effect of NPWT (mostly PICO or Prevena) on wound complications in obese women after cesarean birth.[55] Ten RCTs with 5583 patients were included in this study. Meta-analysis results suggested a significant difference favoring the NPWT group [relative risk(RR) 0.79, 95% CI 0.65 to 0.95, p<0.01], indicating an absolute risk reduction of 1.8% among those receiving NPWT compared to usual care. This study also reports a significant higher risk of blistering in the NPWT group.

Darwisch (2020) published an RCT to evaluate NPWT as a prevention and therapy of superficial infection.[56] In this single-center prospective randomized controlled trial, patients after cardiac surgery performed via median sternotomy (n = 528) were after stratification according to the marker body mass index (BMI ≥35 yes/no) randomized to receive either a disposable PICO dressing (PD) (n = 56/193) or a standard dry dressing (SDD) (n = 66/213) over the incision immediately at the conclusion of surgery. The authors report that use of PICO dressing NPWT compared with SDD did not improve the rate of SSIs in 30 days, but PD treatment reduced the rate of deep type of SSIs; so, there is a shift toward more superficial SSIs.

Prevena System

Pauser (2016) reported on a small RCT (n=21) evaluating Prevena in patients who had hemiarthroplasty for femoral neck fractures.[57] Use of the Prevena System significantly reduced seroma size, days of wound secretion, wound care time, and need for dressing changes.

Grauhan (2013) published a controlled clinical trial to evaluate negative pressure wound dressing treatment for the prevention of infection.[58] For this study, 150 consecutive obese patients (body mass index ≥ 30) with cardiac surgery performed via median sternotomy were analyzed. The authors concluded that Negative pressure wound dressing treatment over clean, closed incisions for the first six to seven postoperative days significantly reduces the incidence of wound infection after median sternotomy in a high-risk group of obese patients.

Murphy (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 blinded endpoint controlled 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).[59] The was no significant difference in the incidence of SSI at 30 days post-surgery between the Prevena and control groups (32% vs. 34%; p=0.68). No significant difference in length of hospital stay was reported.

Hussamy (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).[60] 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 (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).[61] The risk of superficial or deep SSI was not significantly different between groups (difference, 0.36%; 95% CI, -1.46% to 2.19%; p=0.70). 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<0.001) and futility for the primary outcome.

Bertges (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).[62] 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=0.55).

Kim (2020) published a meta-analysis to determine the effective indications of closed-incisional negative-pressure wound therapy (ciNPWT) following total hip or knee arthroplasty.[63] The systematic search was performed on MEDLINE, Embase, and Cochrane Library, and 11 studies were included. The studies comparing ciNPWT and conventional dressings were categorized into the following subgroups based on patient risk and revision procedures: routine vs high-risk patient; primary vs revision arthroplasty. These studies either used the Prevena or PICO system for the ciNPWT. Overall the analysis found that the wound complication (odds ratio [OR] = 0.38; 95% confidence interval [CI] 0.15 to 0.93; p=0.030) and surgical site infection (SSI) (OR=0.24; 95% CI = 0.09 to 0.64; p=0.005) in high-risk patients were significantly lower than the routine patients after ciNPWT. Further, in cases involving revision arthroplasties, the overall rates of wound complication (OR=0.33; 95% CI = 0.18 to 0.62; p<0.001) and SSI (OR=0.26; 95% CI = 0.11 to 0.66; p=0.004) were significantly lower in the ciNPWT.

Cooper (2022) published an RCT to assess whether ciNPWT could decrease SSCs in high-risk patients undergoing direct anterior (DA) approach to total hip arthroplasty (THA).[64] This prospective RCT enrolled high-risk DA THA patients at three centers. Patients were offered enrollment if they had previously identified risk factors for surgical site complications (SSC): Body mass index (BMI) greater than 30 kg/m^2, diabetes, active smoking, or prior hip surgery. Patients were randomized after closure to either an occlusive (control) dressing or ciNPWT (Prevena) dressing for seven days. One hundred and twenty two patients enrolled; 120 completed data collection. SSCs occurred in 18.3% (11/60) of control patients compared to 8.3% (5 of 60) of ciNPT patients ($\chi 2 = 2.60$, p =0.107). SSCs included dehiscence to the subcutaneous level and prolonged drainage. Nine control (15.0%) and two ciNPWT (3.3%) patients met CDC criteria for superficial surgical site infection (SSI) ($\chi 2=4.90$, p=0.027). Overall, there was a significant reduction in superficial SSIs and a trend toward lower SSCs after ciNPWT.

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

SUMMARY OF EVIDENCE

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

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. 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 DFUs, but was not duplicated in the per protocol population due to a high number of exclusions. One study of the Smart Negative Pressure nonpowered Wound Care System (SNaP) 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic pressure ulcers who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. All trials are of low-quality and at high-risk of bias. Also, most study populations were treated in inpatient settings. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have lower-extremity ulcers due to venous insufficiency who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. 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. The

evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have traumatic or surgical wounds who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. There are limited data on NPWT as a primary treatment of partial-thickness burns. One RCT found no benefit of NPWT on graft take and wound epithelialization in patients with full-thickness burns. Another RCT found a significant decrease in time to wound closure in patients with wound healing impairment following abdominal surgery; however, it is unclear if this difference is clinically meaningful. In other studies, NPWT showed no benefit in the treatment of patients with surgical wounds or skin grafts healing by primary intention, and a systematic review of NPWT for traumatic and surgical wounds found no differences between standard dressing and NPWT for any wound outcome measure. However, a small RCT has suggested that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. A small retrospective study reported improved epithelialization with NPWT in patients free of comorbidities. Additional study in larger, outpatient samples is needed to evaluate this outcome measure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have traumatic or surgical wounds who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use after total joint arthroplasty. The evidence base for the Prevena System is not sufficiently robust for conclusions on efficacy to be drawn. Well-designed comparative studies with larger numbers of patients treated in an outpatient setting are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For obese women undergoing cesarean delivery, there is evidence for NPWT that indicate a significant reduction in surgical site infection. But the contradictory nature of other results of this procedure in obese women undergoing cesarean deliveries suggest that more studies are needed to reach a consensus about use of NPWT in this situation.

PRACTICE GUIDELINE SUMMARY

INTERNATIONAL EXPERT PANEL ON NEGATIVE PRESSURE WOUND THERAPY

In 2011, an international expert panel on NPWT provided evidence-based recommendations for the use of NPWT in chronic wounds.[65] The panel made the following recommendations for the use of NPWT (see Table 3).

Table 3. Recommendations on Use of NPWT in Chronic Wounds

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

NPWT: negative pressure wound therapy.

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

INTERNATIONAL MULTIDISCIPLINARY CONSENSUS RECOMMENDATIONS

Willy (2017) presented evidence-based consensus guidelines on the use of closed incision negative pressure therapy (ciNPT) following surgery.[66] Among the studies found were 100 randomized controlled studies on ciNPT, most of which found an association between the use of ciNPT and improved outcomes. Based on the evidence, the consensus panel recommended that surgeons evaluate risk in patients before surgery to determine whether patient comorbidities (ie, obesity or diabetes) or the nature of the surgery presents an increased danger of infection. In such cases, the panel recommended the use of ciNPT.

INFECTIOUS DISEASES SOCIETY OF AMERICA AND SURGICAL INFECTION SOCIETY

In 2011, guidelines for the prevention of infections associated with combat-related injuries were endorsed by the Infectious Diseases Society of America and the Surgical Infection Society.[67] The guidelines provided an IB recommendation (strong recommendation, moderate-quality evidence) that NPWT should be used to manage open wounds (excluding central nervous system injuries).

The 2012 guidelines from the Society for the diagnosis and treatment of diabetic foot infections stated that no adjunctive therapy has been proved to improve the resolution of infection, but for select diabetic foot wounds that are slow to heal, clinicians might consider using NPWT (weak recommendation, low-quality evidence).[68]

AMERICAN COLLEGE OF PHYSICIANS

In 2015, the American College of Physicians published guidelines on the treatment of pressure ulcers.[69] The guidelines stated there was low-quality evidence that the overall treatment effect of NPWT did not differ from the standard of care.

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. NPWT was included as a potential second-line intervention if first-line treatments did not result in wound healing (level B evidence). The guidelines indicated that patients must be selected carefully for this procedure. The guidelines were updated in 2014 with additional validation.[70]

In 2010, the AAWC published guidelines on the care of venous ulcers.[71] 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 WORKING GROUP ON THE DIABETIC FOOT

In 2020, the International Working Group on the Diabetic Foot (IWGDF) published updated guidelines on use of interventions to enhance healing of chronic foot ulcers in diabetes.[72] The updated guidelines make the following recommendations:

- "Consider the use of negative pressure wound therapy to reduce wound size, in addition to best standard of care, in patients with diabetes and a post-operative (surgical) wound on the foot. (GRADE strength of recommendation: Weak; Quality of evidence: Low)"
- "We suggest not using negative pressure wound therapy in preference to best standard of care in nonsurgical diabetic foot ulcers. (GRADE strength of recommendation: Weak; Quality of evidence: Low)"

THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

In 2023, the American Academy of Orthopaedic Surgeons (AAOS) released a clinical practice guideline on the prevention of surgical site infection after major extremity trauma.[73] The guideline is based on a systematic review conducted by the AAOS and the Department of Defense. Each recommendation is rated based on the strength of supporting evidence. The recommendations for the use of NPWT for open and closed fractures was rated as strong (high quality supporting evidence):

- "After closed fracture fixation, negative pressure wound therapy may mitigate the risk of revision surgery or surgery site infections; however, after open fracture fixation, negative pressure wound therapy does not appear to offer an advantage when compared with sealed dressings as it does not decrease wound complications or amputations."

SUMMARY

One-Month Therapeutic Trial

Overall, the evidence from comparative clinical trials has demonstrated there is a subset of problematic wounds for which the use of powered negative pressure wound therapy (NPWT) may provide a significant clinical benefit. In addition, clinical practice guidelines recommend outpatient NPWT in some situations. Therefore, a one-month therapeutic trial of a NPWT system (pump and supplies) may be considered medically necessary when criteria are met.

The evidence does not show that negative pressure wound therapy (NPWT) improves health outcomes when criteria are not met. Therefore, a one-month therapeutic trial of a NPWT

system (pump and supplies) is considered not medically necessary when criteria are not met.

Continuation After One-Month Therapeutic Trial

Overall, the evidence from comparative clinical trials has demonstrated there is a subset of problematic wounds for which the *continuation* of powered negative pressure wound therapy (NPWT) following a one-month trial may provide a significant clinical benefit when there is appropriate supervision and documentation. Therefore, *continuation* of the powered NPWT system may be considered medically necessary when criteria are met.

When there is not documentation of a licensed medical professional assessing the wound and/or the wound is not improving, the *continuation* of powered negative pressure wound therapy at any period of time following a one-month therapeutic trial is therefore considered not medically necessary.

The evidence does not show that negative pressure wound therapy (NPWT) improves health outcomes beyond four months. Therefore, continuation of NPWT after four total months is considered not medically necessary.

Single-Use NPWT Systems

There is not enough evidence to establish the safety and efficacy of single-use NPWT systems. Well-designed comparative studies with larger numbers of patients treated in an outpatient setting are needed. Therefore, single-use NPWT systems (powered or nonpowered) is considered investigational for the treatment of acute or chronic wounds.

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CODES

Codes	Number	Description
CPT	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	;total wound(s) surface area greater than 50 square centimeters
	97607	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
	97608	;total wound(s) surface area greater than 50 square centimeters
HCPCS	A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
	A7000-A7001	Canister for use with suction pump, code range
	A9272	Wound suction, disposable, includes dressing and 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

Codes	Number	Description
	K0744-K0746	Code range for absorptive wound dressings to be used with home suction pump coded with K0743

Date of Origin: *December 2021*