1.01.16	Negative Pressure Wound Therapy in the Outpatient Setting		
Original Policy Date:	June 13, 2001	**Effective Date:**	March 1, 2024
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 34

Policy Statement

Initiation of Powered Negative Pressure Wound Therapy

I. An initial therapeutic trial of not less than 2 weeks using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling risk factors (e.g., diabetes, nutrition, relief of pressure), may be considered **medically necessary** for **any** of the following:
   A. Chronic (greater than 90 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care with **any** of the following:
      1. High-volume drainage that interferes with healing is present
      2. Standard dressings cannot be maintained due to anatomic factor
   B. Wounds in individuals with underlying clinical conditions that are known to negatively impact wound healing, which are nonhealing (at least 30 days), despite optimal wound care. (Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the NPWT.)
   C. Traumatic or surgical wounds with **both** of the following:
      1. There has been a failure of immediate or delayed primary closure
      2. There is documentation of **one or more** of the following:
         a. Exposed bone within the wound
         b. Exposed cartilage within the wound
         c. Exposed tendon within the wound
         d. Visible foreign material within the wound

Continuation of Powered Negative Pressure Wound Therapy

II. Continuation of the powered NPWT system, following an initial 2-week therapeutic trial as part of a comprehensive wound care program, may be considered **medically necessary** with **all** of the following:
   A. The treatment trial has resulted in documented objective improvements in the wound(s)
   B. There will be ongoing objective improvement during subsequent treatment

III. The following are considered **investigational**:
   A. Continuation of the powered NPWT system when the therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound
   B. Continuation of the powered NPWT system when the wound has developed evidence of wound complications contraindicating continued NPWT
   C. Continuation of the powered NPWT system when the wound has healed to the extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments
   D. Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above
   E. Use of single-use NPWT systems (powered or nonpowered for the treatment of acute or chronic wounds, including but not limited to diabetic, venous, surgical, and traumatic wounds

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Underlying Clinical Condition

If malnourished, nutrition will be addressed simultaneously with the NPWT.

Note: A powered NPWT system initiated by a provider for wound care in the inpatient setting would be allowed up to1 month in the initial transfer to the outpatient setting to provide continuity of care.

Pressure Ulcer Advisory Panel Staging System	
Stage I	Non-blanchable erythema of intact light toned skin, or darker or violet hue in darkly pigmented skin
Stage II	Partial thickness skin loss involving epidermis and/or dermis
Stage III	Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia
Stage IV	Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures

Objective Improvements

Objective improvements in the wound should include the development and presence of healthy granulation tissue, progressive wound contracture and decreasing depth, and/or the commencement of epithelial spread from the wound margins.

Contraindications to the use of negative pressure wound therapy (NPWT) systems include the following conditions as noted in a 2009 U.S. Food and Drug Administration (FDA) alert:

- Necrotic tissue with eschar
- Untreated osteomyelitis
- Nonenteric and unexplored fistulae
- Malignancy in the wound
- Exposed nerve
- Exposed anastomotic site
- Exposed organ

In a 2011 update, FDA noted additional deaths and injury reports with NPWT since 2009. Although rare, these complications can occur wherever NPWT systems are used, including hospitals, long-term care facilities, and at home. Bleeding was the cause of the most serious adverse events, including deaths. Most reports of wound infection were related to the retention of dressing pieces in the wounds. Recommendations for health care providers include the following: select individuals for NPWT carefully knowing that NPWT systems are contraindicated for certain wound types, and individual risk factors must be thoroughly considered before use; assure that the individual is monitored frequently in an appropriate care setting by a trained practitioner; be aware of complications associated with dressing changes such as infection and bleeding; be vigilant for potentially life-threatening complications, such as bleeding; and be prepared to take prompt action if they occur. The FDA reported that the safety and effectiveness of NPWT systems in newborns, infants, and children had not been established and, currently, there are no NPWT systems cleared for use in these populations.

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

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

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

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

Coding

The following HCPCS codes describe NPWT using an electrical pump:

- **A6550**: Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
- **E2402**: Negative pressure wound therapy electrical pump, stationary or portable

The following HCPCS codes were developed specific to an NPWT system (such as the Kalypto® system), in which the exudate is collected in the dressing rather than in a canister:

- **K0743**: Suction pump, home model, portable, for use on wounds
- **K0744-K0746**: Code range for absorptive wound dressings to be used with home suction pump coded with K0743

The following HCPCS code was developed for a disposable NPWT system (e.g., the SNaP® [Smart Negative Pressure] or PICO™ systems):

- **A9272**: Wound suction, disposable, includes dressing, all accessories and components, any type, each

There are 2 CPT codes for application of NPWT using durable medical equipment:

- **97605**: Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
- **97606**: Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

There are also CPT codes for application of NPWT using disposable, nondurable equipment:

- **97607**: Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
- **97608**: Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

Description

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

Related Policies

- Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions
- Bioengineered Skin and Soft Tissue Substitutes
- Electrostimulation and Electromagnetic Therapy for Treating Wounds
- Noncontact Ultrasound Treatment for Wounds

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Negative pressure therapy or suction devices cleared by the U.S. Food and Drug Administration (FDA) for treating chronic wounds include, but are not limited to: Vacuum-Assisted Closure® Therapy (V.A.C., also known as negative pressure wound therapy; 3M™/KCI); Versatile 1™ (V1) Wound Vacuum System (Blue Sky Medical), RENASYS™ EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical Electronics), SVED® (Cardinal Health), and PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew).

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

A nonpowered NPWT device, the SNaP® Wound Care System (now SNAP™ Therapy System) (3M™/ previously Spiracur, acquired by Acelity in 2015), 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.

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

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

In November 2009, the FDA issued an alert concerning complications and deaths associated with NPWT systems. An updated alert was issued in February 2011.[1,]
FDA product code: OMP.

Rationale

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 (i.e., 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 (i.e., healing by secondary intention) or preparation for wound closure with skin grafts or flaps (i.e., healing by primary intention). Therefore, debridement, irrigation, whirlpool treatments, and wet-to-dry dressings are common components of chronic wound care.

Negative pressure wound therapy (NPWT) 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function¾including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects.

Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

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

This review was informed by a 2000 TEC Assessment that evaluated negative pressure therapy of pressure ulcers, venous ulcers, and diabetic ulcers.[2,] Literature updates for this review have focused on comparative trials with the features described in the 2000 TEC Assessment (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 negative pressure wound therapy (NPWT) for the healing of acute wounds.

Negative pressure wound therapy 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:[3,]

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

Generally, in a heterogeneous population, the evidence is uncertain for home use of NPWT. The authors of a systematic review for the Agency for Healthcare Research and Quality and the Centers for Medicare & Medicaid Services (2014) reported that due to insufficient evidence, they were unable to draw conclusions about the efficacy or safety of NPWT in the home setting.[4,] There were 3 retrospective cohort studies on diabetic foot ulcers and arterial ulcers, an RCT and 2 retrospective cohort studies on pressure ulcers, and a retrospective cohort on venous ulcers. Six studies used the V.A.C., and the other used the Smart Negative Pressure (SNaP) Wound Care System device.

Reviewers found that interpretation of available data was limited by variability in the types of comparator groups, methodologic limitations, and poor reporting of outcomes.[5,] 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.[6,]

Diabetic Lower-Extremity Ulcers and Amputation Wounds

Clinical Context and Therapy Purpose

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

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

Populations

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

Interventions

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

Comparators

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

Outcomes

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.
- Studies conducted exclusively in the inpatient setting were excluded.

Review of Evidence

Systematic Reviews

A 2013 Cochrane review of NPWT for treating foot wounds in patients with diabetes[7,] was updated in 2018 to include 11 RCTs (N=972) with sample sizes ranging from 15 to 341 participants.[8,] Two studies addressed post-amputation wounds and all other studies described treatment of diabetic foot ulcers. Only 1 study comparing NPWT and moist dressings for post-amputation wounds reported a follow-up time (n=162), and a statistically significant improvement in the proportion of wounds healed (risk ratio [RR], 1.44; 95% confidence interval [CI], 1.03 to 2.01) was demonstrated after a follow-up

duration of 16 weeks. The median time to healing was 21 days shorter for the NPWT group (hazard ratio [HR], 1.91; 95% CI, 1.21 to 2.99) compared with moist dressings. Data from 3 studies suggest that people with diabetic foot ulcers allocated to NPWT may be at reduced risk of amputation compared to moist dressings (RR, 0.33; 95% CI, 0.15 to 0.70; I^2=0%). Reviewers concluded that there was some evidence to suggest that NPWT was more effective than standard care, but the findings were uncertain due to the risk of bias in the unblinded studies. Reviewers recommended further study to reduce uncertainty around decision-making.

A systematic review by Wynn and Freeman (2019) evaluating NPWT for diabetic foot ulcers reported similar benefits in wound healing and the reduction of amputation incidence.[9,] However, reviewers emphasized limitations in the present body of evidence, including methodological flaws such as the absence of validated tools for the measurement of wound depth and area, lack of statistical power calculations, and heterogeneity in pressure settings employed during therapy.

A systematic review and meta-analysis by Chen et al (2021) evaluating NPWT for diabetic foot ulcers compared to standard care reported a significant improvement in the wound healing rate with NPWT (odds ratio [OR], 3.60; 95% CI, 2.38 to 5.45; p<.001) based on 6 RCTs representing 536 patients.[10,] No significant difference in the incidence of adverse events was reported between groups (OR, 0.49; 95% CI, 0.10 to 2.42; p=.38). The reviewers noted several limitations in the body of evidence, including lack of blinding, unclear follow-up durations, and heterogeneous pressure settings.

Section Summary: Diabetic Lower-Extremity Ulcers and Amputation Wounds

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

Portable, Single-Use Therapy for Diabetic Lower-Extremity Ulcers and Amputation Wounds

Clinical Context and Therapy Purpose

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

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

Populations

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

Interventions

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

Comparators

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

Outcomes

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.
- Studies conducted exclusively in the inpatient setting were excluded.

Review of Evidence

PICO Dressing

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

Kirsner et al (2019) published an RCT that allocated 164 patients with venous leg ulcers (n=104) or diabetic foot ulcers (n=60) to treatment with PICO single-use NPWT (s-NPWT; n=80) or traditional, reusable NPWT systems (t-NPWT; n=84).[11,] Prior to randomization, patients were excluded if a reduction in target ulcer area ≥30% was achieved with compression or offloading during a 2-week run-in period as a way to exclude 'quick healers'. Three patients in the t-NPWT arm were excluded from the intention-to-treat analysis. For the per-protocol analysis, 16 (20%) and 30 (37%) patients were excluded from the s-NPWT and t-NPWT arms, respectively. Randomization was stratified by wound type and wound size. The PICO dressing was set to provide -80 mmHg of negative pressure. Choice of traditional, NPWT device manufacturer and pressure setting was at the discretion of the treating physician, with an average pressure of -118.3 mmHg (median, -125 mmHg; standard deviation [SD], 23.4 mmHg) applied.

The study intended to test for noninferiority in the percentage change of target ulcer area with s-NPWT versus t-NPWT over the course of a 12-week treatment period, with a noninferiority margin of 12.5%. The analysis was performed with the per-protocol population to account for dropouts and then repeated on the full analysis set (intention-to-treat). Secondary outcomes included wound closure rate, time to wound closure, and quality of life. Participants and investigators were not blinded, and it is unclear if the study utilized blinded assessors. Patients were seen weekly in outpatient wound centers. After adjustment for baseline wound area, pooled study site, wound type, and wound duration at baseline, the mean percentage difference in wound area over 12 weeks was 27% (96.9% vs. 69.9%; p=.003) in the per-protocol analysis and 39.1% (90.24% vs. 51%; p<.001) in the intention-to-treat analysis. This treatment effect was also significant in the diabetic foot ulcer subgroup (p=.031). However, confidence intervals were not reported for the primary outcome. Confirmed wound closure (intention-to-treat) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted OR of 0.294 (95% CI, 0.135 to 0.638; p=.002) for all wound types and 0.161 (95% CI, 0.035 to 0.744; p=.020) for diabetic foot ulcer. However, the subgroup analysis for diabetic foot ulcer patients in the per-protocol population was not significant.

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

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

Smart Negative Pressure Wound Care System

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

Armstrong et al (2011) reported on the results of a planned interim analysis of an RCT comparing the SNaP Wound Care System with the V.A.C. Therapy for the treatment of chronic lower-extremity wounds.[13,] Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.[14,] The trial enrolled 132 patients with lower-extremity venous or diabetic ulcers with a surface area between 1 cm^2 and 100 cm^2 and diameter less than 10 cm present for more than 30 days despite appropriate care. Approximately 30% of patients in this study had diabetic ulcers, and no subgroup analyses were conducted. Dressings were changed per the manufacturer's direction: 2 times per week in the SNaP group and 3 times per week in the V.A.C. group. Patients were assessed for up to 16 weeks or until complete wound closure; 83 (63%) patients completed the study. Intention-to-treat analysis with the last observation carried forward showed noninferiority in the primary outcome of wound size reduction at 4, 8, 12, and 16 weeks. When adjusted for differences in wound size at baseline, SNaP-treated subjects showed noninferiority to V.A.C.-treated subjects at 4, 12, and 16 weeks. Kaplan-Meier analysis showed no significant difference in complete wound closure between the 2 groups. At the final follow-up, 65.6% of the V.A.C. group and 63.6% of the SNaP group had wound closure. Survey data indicated that dressing changes required less time with the SNaP device and use of the SNaP device interfered less with mobility and activity than the V.A.C. device.

A 2010 retrospective study with historical controls compared NPWT using the SNaP device (n=28) with wound care protocols using Apligraf, Regranex, and skin grafting (n=42) for the treatment of lower-extremity ulcers.[15,] Seven (25%) patients in the SNaP-treated group could not tolerate the treatment and were discontinued from the study because of complications; they were considered treatment failures. Between-group estimates of time-to-wound healing by Kaplan-Meier analysis favored the SNaP treatment group. This study is limited by the use of historical controls, multiple modalities to treat controls, and a large number of dropouts. Subgroup analyses for patients with diabetic (50%) and venous (50%) ulcers were not available. The authors noted that patients in the SNaP-treated group might have benefited from being in an experimental environment, particularly

because wounds in this group were seen twice per week compared with variable follow-up in historical controls.

Section Summary: Portable, Single-Use Therapy for Diabetic Lower-Extremity Ulcers and Amputation Wounds

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

Chronic Pressure Ulcers

Clinical Context and Therapy Purpose

The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with chronic pressure ulcers.
The following PICO was used to select literature to inform this review.

Populations

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

Interventions

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

Comparators

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

Outcomes

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.
e. Studies conducted exclusively in the inpatient setting were excluded.

Review of Evidence

Systematic Reviews

A 2015 Cochrane review included 4 RCTs of NPWT (N=149) for treating pressure ulcers in any care setting, although most of the patients were treated in a hospital setting.[7,] Three trials were considered to be at high risk of bias, and all evidence was considered to be of very low quality. Only 1 trial reported on complete wound healing, which occurred in only 1 of the 12 study participants. Reviewers concluded there is high uncertainty about the potential benefits and/or harms for this indication. An update of this Cochrane review was published in 2023 and included 8 RCTs (N=327).[16,] However, there were no additional trials that reported on complete wound healing. Reviewers similarly concluded that available evidence is of poor quality and conclusions drawn should be interpreted with considerable caution.

Randomized Controlled Trials

One representative trial, from 2003 (noted in the 2015 Cochrane review as "awaiting further information from the authors"), randomized 24 patients with pressure ulcers of the pelvic region to NPWT or standard wound care.[17,] All patients with pelvic pressure ulcers were eligible for enrollment and were not required to be refractory to standard treatment. There was no significant group difference for the main outcome measure, time to 50% reduction of wound volume (mean, 27 days in the NPWT group vs. 28 days in the control group). Findings were limited by the small number of patients in the study, the possibility that the control group might not have received optimal wound management, and lack of information on the time to complete wound healing.

Section Summary: Chronic Pressure Ulcers

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

Lower-Extremity Ulcers due to Venous Insufficiency

Clinical Context and Therapy Purpose

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

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

Populations

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

Interventions

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

Comparators

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

Outcomes

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Randomized Controlled Trials

A 2015 Cochrane review of NPWT for venous insufficiency identified a single RCT with 60 patients.[18,]This trial, published by Vuerstaek et al (2006), was performed in an inpatient setting in conjunction with skin grafts and compared the efficacy of NPWT using the V.A.C. system (n=30) with conventional moist wound care (n=30) in patients hospitalized with chronic venous and/or arterial leg ulcers of greater than 6 months in duration.[19,] Full-thickness punch skin grafts from the thigh were applied, followed by 4 days of NPWT or conventional care to assure complete graft adherence. Each group then received standard care with nonadhesive dressings and compression therapy until complete healing (primary outcome) occurred. The median time to complete healing was 29 days in the NPWT group and 45 days in the control group (p=.001). Ninety percent of ulcers treated with NPWT healed within 43 days, compared with 48% in the control group. These results would suggest that NPWT significantly hastened wound healing, although the use of skin autografts makes it difficult to discern the contribution of NPWT to the primary outcome. The 2015 Cochrane review did not identify any RCT evidence on the effectiveness of NPWT as a primary treatment for leg ulcers, nor was there any evidence on the use of NPWT in the home setting.

Section Summary: Lower-Extremity Ulcers due to Venous Insufficiency

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

Portable, Single-Use Therapy for Lower-Extremity Ulcers due to Venous Insufficiency

Clinical Context and Therapy Purpose

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

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

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

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

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

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

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

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

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.
- Studies conducted exclusively in the inpatient setting were excluded.

Review of Evidence
PICO Dressing
Kirsner et al (2019) published an RCT that allocated 164 patients with venous leg ulcers (n=104) or diabetic foot ulcers (n=60) to treatment with PICO s-NPWT (n=80) or t-NPWT (n=84).[11,] Additional study details and limitations are summarized previously in indication 2.

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

for venous leg ulcer. The subgroup analysis for venous leg ulcer patients in the per protocol population was also not significant.

Smart Negative Pressure Wound Care System

Armstrong et al (2011) reported on results of a planned interim analysis of an RCT comparing the SNaP Wound Care System with the V.A.C. Therapy for the treatment of chronic lower-extremity wounds.[13,] Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012.[14,] Approximately 70% of the study population had venous leg ulcers. Additional study details and limitations are summarized previously in indication 2.

A subgroup analysis (2015) of 40 patients with venous leg ulcers who completed the study showed a significant improvement in the percentage of those with complete wound closure treated with SNaP (57.9%) compared with the V.A.C. system (38.2%; p=.008).[20,] However, this study had a high loss to follow-up and lacked a comparison with standard treatment protocols.

Section Summary: Portable, Single-Use Therapy for Lower-Extremity Venous Ulcers

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

Burn Wounds

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals with burn wounds.

Interventions

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

Comparators

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

Outcomes

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

- Incidence of complete wound closure.

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

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.[21,] The abstract did not provide enough evidence to draw any conclusions on the efficacy of NPWT on partial-thickness burn wounds.

Not included in the Cochrane review was a trial by Bloemen et al (2012) on the effect of NPWT on graft take in full-thickness burn wounds.[22,] This multicenter, 4-armed RCT enrolled 86 patients and compared a split-skin graft with or without a dermal substitute (MatriDerm), with or without NPWT. Outcome measures included graft take at 4 to 7 days after surgery, the rate of wound epithelialization, and scar parameters at 3 and 12 months postoperatively. Graft take and wound epithelialization did not differ significantly between groups. Most measures of scar quality also did not differ significantly between groups.

An expert panel convened to develop evidence-based recommendations for the use of NPWT reported that the evidence base in 2011 was strongest for the use of NPWT on skin grafts and weakest as a primary treatment for burns.[23,]

Case Series

A retrospective case series by Ehrl et al (2017) examined outcomes for 51 patients treated for burned hands with topical NPWT at a single-center; of the initial 51 patients, only 30 patients (47 hands) completed follow-up, which was conducted an average of 35 months after injury and included physical examination.[24,]Before NPWT, patients received escharotomy or superficial debridement if needed, or split-thickness skin grafts for third-degree burns; the NPWT gloves used allowed caregivers to assess patients' fingertips for perfusion. Ergotherapy was initiated following evidence of epithelialization. Primary endpoints were a dorsal extension of the fingers and capability of complete active fist closure, with the majority of patients achieving 1 or both outcomes: the first endpoint was reached in 85.1% (n=40) of the cases; the second endpoint was reached in 78.7% of hands (n=37). When evaluated using the Disabilities of the Arm, Shoulder, and Hand questionnaire (scoring range, 0-100; with 0=no disability), patients with injuries resulting in hypertrophic scarring had significantly worse scores (28.8) than patients without similar scarring (11.7; p<.05). Despite a number of limitations, including heterogeneity of burned areas (2.5% to 70% throughout the series), the authors acknowledged NPWT as standard treatment at the institution from which these data were drawn.

Section Summary: Burn Wounds

The evidence on NPWT as a primary treatment of partial-thickness burns is limited. A retrospective case series reported good functional outcomes in most patients treated for hand burns with NPWT.

One RCT on NPWT for skin grafts showed no benefit for graft take, wound epithelialization, or scar quality.

Traumatic and Surgical Wounds

Clinical Context and Therapy Purpose

The purpose of outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with traumatic or surgical wounds.
The following PICO was used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is outpatient NPWT.

Comparators

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

Outcomes

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Identified studies have described various wound types treated over periods ranging from several days to several months. Studies also differed by whether NPWT was used for nonhealing wounds or as a prophylactic treatment for surgical wounds in patients at high risk for nonhealing.

Review of Evidence

Systematic Reviews

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

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

Review	RCT	Other Studies	Participants[1]	N (Range)	Major Outcomes	Study Quality	Relevance
Cochrane (2022)[25,]	62	6	Individuals with postoperative wounds anticipated to heal by primary closure	13,340 (2 to 2035)	NPWT nonsignificantly reduced mortality and significantly reduced SSI	Unclear or high risk of bias noted	Studies generally included devices of interest; V.A.C. (n=7), PICO (n=20), PREVENA (n=24); however, outpatient use is often unspecified and may be limited
Li et al (2019)[26,]	45	0	Adult surgical patients	6624 (30 to 876)	SSIs were significantly lower; all other outcomes NSD	Certainty of the pooled effect ranked as low due to serious risk of bias	Studies generally included devices of interest; V.A.C. (n=12), PICO (n=11), PREVENA (n=15); however, outpatient use is often unspecified and may be limited
De Vries et al (2016)[27,]	6	15	Individuals treated with prophylactic NPWT in clean and contaminated surgery	RCT: 277 (13 to 141) Other: 1099 (23 to 237)	Surgical site infection (RCT: p=.04; Other: p<.00001; NSD for trauma/orthopedic surgery)	Low quality of evidence due to lack of blinding in outcome assessment	Unclear; focus on inpatient therapy
Cochrane (2018)[28,]	7	0	Individuals with open traumatic wounds (open fractures and other types)	1377 (40 to 586)	Wound infection (NSD)	Unclear or high risk of bias noted	Limited; focus on inpatient therapy

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

A 2022 Cochrane review update evaluated NPWT compared with standard dressings for surgical wound healing by primary closure.[25,] Negative pressure wound therapy was associated with a reduced risk of surgical site infection (SSI) (44 studies [N=11,403]; RR, 0.73; 95% CI, 0.63 to 0.85; I^2=29%). Mortality was lower with NPWT, but this was nonsignificant (11 studies [N=6384]; RR, 0.78; 95% CI, 0.47 to 1.30). No significant difference was found for wound dehiscence, reoperations, or wound-related readmission. The analysis is limited by inclusion of studies with mixed or unclear

intervention types, no subgroup analysis for traditional or portable, single-use systems, and no discussion of use specific to outpatients.

A systematic review and meta-analysis by Li et al (2019) was conducted comparing the effectiveness and safety of NPWT with standard surgical dressing or conventional therapy for the prevention of SSI.[26,] A total of 45 RCTs assessing 6624 adult patients were included for analysis. Studies utilized a variety of NPWT devices, including V.A.C., PICO, and Prevena systems. Inclusion criteria did not impose restrictions on SSI grading systems or on surgery types. Surgeries for infected or chronic non-healing wounds including diabetic, venous, and arterial ulcers were excluded. Overall, NPWT was associated with a 40% reduction in SSI risk compared to control, with moderate heterogeneity (RR, 0.58; 95% CI, 0.49 to 0.69; I^2=19%; p<.00001). This significant reduction in risk was particularly maintained in high-risk surgical patients (32 RCTs; RR, 0.60; 95% CI, 0.50 to 0.73; I^2=23%; p<.00001). There was no significant effect of NPWT on wound dehiscence, hematoma occurrence, hospital admission, or length of hospital stay. The certainty of the evidence based on GRADE criteria was graded as low to very low due to the serious risk of bias stemming from lack of blinding and methodological flaws in SSI assessment and standardization. The authors suggest that further studies are warranted to elucidate the optimal protocol for NPWT utilization.

A systematic review and meta-analysis by De Vries et al (2016) included 6 RCTs and 15 observational studies of SSIs after prophylactic NPWT.[27,] One study selected used a portable device (PICO), while the others used a V.A.C. Unlike the 2014 Cochrane review, studies on skin grafts were not included. Meta-analysis of the RCTs showed that the use of NPWT reduced the rate of SSIs (OR, 0.56; 95% CI, 0.32 to 0.96; p=.04), and reduced the SSI rate from 140 to 83 per 1000 patients. However, the quality of evidence was rated as low due to the high risk of bias in the nonblinded assessments and imprecision in the estimates. Subgroup meta-analysis of 4 RCTs in orthopedic/trauma surgery did not demonstrate significant benefit in regards to reducing the risk of SSI (OR, 0.58; 95% CI, 0.32 to 1.07).

A 2018 Cochrane review evaluated the effects of NPWT for open traumatic wounds (e.g., open fractures or soft tissue wounds) managed in any care setting.[28,] Seven RCTs were identified for the review with sample sizes ranging from 40 to 586 participants. Four studies (n=596) compared NPWT at 125 mmHg with standard care for open fracture wounds. Pooled data revealed no significant difference between groups in the number of participants with healed wounds (RR, 0.48; 95% CI, 0.81 to 1.27; I^2=56%). Pooled data from 2 studies (n=509) utilizing NPWT at 125 mmHg on other open traumatic wounds demonstrated no significant difference in risk of wound infection compared to standard care (RR, 0.61; 95% CI, 0.31 to 1.18). One study (n=463) assessing NPWT at 75 mmHg against standard care in other open traumatic wounds did not demonstrate a significant difference in wound infection risk (RR, 0.44; 95% CI, 0.17 to 1.10). One study comparing NPWT at 125 mmHg against 75 mmHg in other open traumatic wounds also failed to demonstrate a significant difference in wound infection risk (RR, 1.04; 95% CI, 0.31 to 3.51). Evidence was deemed low to very low in certainty and quality due to imprecision and risk of bias.

Randomized Controlled Trials

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

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

Study; Trial	Surgery Received	No. of Participants	Notes on NPWT effectiveness	P-value
Stannard (2012)[29,]	Various, after fractures and other trauma	249	Fewer infections, less discharge than standard closure	.049
Costa (2018); WOLLF[30,]	Severe open fracture of the lower limb	460	NSD in self-rated disability, number of deep SSI, or QOL scores	Disability:.13 SSI:.64 QOL: NR
Seidel (2020); SAWHI[31,]	Subcutaneous abdominal wound healing impairment	539 (randomized) 507 (modified	Shorter time to wound closure and higher wound closure rate	<.001

Study; Trial	Surgery Received	No. of Participants	Notes on NPWT effectiveness	P-value
		intention-to-treat) 310 (per protocol)		

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

One of the larger studies on prophylactic NPWT for surgical wounds is a report from an investigator-initiated, industry-sponsored multicenter RCT of inpatient NPWT for closed surgical incisions by Stannard et al (2012).[29,] (A preliminary report was published in 2006.)[32,] Participants included 249 blunt trauma patients with 263 high-risk fractures (tibial plateau, pilon, calcaneus) requiring surgical stabilization. Patients were randomized to NPWT applied to the closed surgical incision or to standard postoperative dressings. All trial participants were maintained as inpatients until wound drainage was minimal, at which time NPWT was discontinued (mean, 59 hours; range, 21 to 213 hours). Patients in the NPWT group were ready for discharge in 2.5 days compared with 3.0 days for the control group (the difference was not statistically significant). The NPWT group had significantly fewer infections (10% of fractures) than the control group (19% of fractures; p=.049). Wound dehiscence after discharge was observed less frequently in the NPWT group (8.6%) than in the control group (16.5%). These results would support the efficacy of the short-term use of NPWT when used under highly controlled conditions of inpatient care, but not the effectiveness of NPWT in the outpatient setting. A small 2015 RCT (n=20) of NPWT in an outpatient setting reported that patients treated with NPWT required significantly fewer dressing changes, reported significantly less pain, and experienced QOL improvements compared with standard wound care.[33,]

The Effect of Negative Pressure Wound Therapy vs Standard Wound Management on 12-Month Disability Among Adults With Severe Open Fracture of the Lower Limb (WOLLF) trial by Costa et al (2018) randomized 460 patients with severe open fracture of the lower limb to NPWT (n=226) or standard wound management (n=234).[30,] The primary outcome was the Disability Rating Index score (range, 0 [no disability] to 100 [completely disabled]) at 12 months, with a minimal clinically important difference of 8 points. Secondary outcomes included deep infection and QOL measures based on the EuroQol 5-dimensions questionnaire. Eighty-eight percent of participants completed the trial. There were no statistically significant differences in disability scores (45.5 vs. 42.4; p=.13), in the number of deep infections (16 [7.1%] vs. 19 [8.1%]; p=.64), or in QOL measures in the NPWT and standard wound management groups, respectively. A 5-year follow-up report found similar patient-reported disability, health-related QOL, or need for surgery in patients treated with NPWT or standard management.[34,] NPWT was used for a limited time frame in the inpatient setting which limits conclusions for the outpatient setting.

The Subcutaneous Abdominal Wound Healing Impairment (SAWHI) multicenter clinical trial by Seidel et al (2020) randomized adult patients with SAWHI to treatment with NPWT (V.A.C. Therapy) or conventional wound therapy (CWT).[31,] The modified intention-to-treat population included 256 and 251 patients assigned to NPWT and CWT, respectively. The primary outcome, mean time to wound closure within 42 days, was significantly shorter in the NPWT group (difference, 3.0 d; 95% CI, 1.6 to 4.4; p<.001) and confirmed via independent, blinded assessors. Additionally, only 35.9% of patients in the NPWT group and 21.5% of patients in the CWT group achieved complete wound closure within 42 days (difference, 14.4%; 95% CI, 6.6% to 22.2%; p<.001). While this met the prespecified non-inferiority margin of 12.5%, the study's statistical model had assumed a complete wound closure rate of 50% in the CWT arm which had not been met within the 42-day treatment period. The benefit of NPWT for these outcomes was sustained in the per-protocol analysis, however, 39% and 31% of patients were excluded from the NPWT and CWT arms, respectively. Primary reasons for exclusion included unauthorized treatment crossovers, insufficient dressing changes, and treatment termination prior to 42 days. More wounds were sutured in the NPWT arm compared to the CWT arm, where more wounds were healed by secondary intention. No significant differences were noted for QOL or pain

measures at any time point. The RR for adverse events (RR, 1.20; 95% CI, 0.97 to 1.47) and wound-related adverse events (RR, 1.51; 95% CI, 0.99 to 2.35) was higher in the NPWT arm. The most frequently documented wound-related adverse events in the NPWT arm included periwound macerations and local infections with signs of inflammation. Overall, it is unclear if a 3-day difference in time to wound closure represents a clinically meaningful benefit. Time to hospital discharge, readmission rates, and duration of outpatient care were not reported; however, in an analysis of resource use, hospitalization time was longer with NPWT than CWT (11.8 days vs. 13.9 days).[35,] Time for dressing changes (196 vs. 278 minutes) and wound-related procedures (167 vs. 266 minutes) were significantly lower with NPWT.

Section Summary: Traumatic and Surgical Wounds

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

Portable, Single-Use Therapy for Traumatic and Surgical Wounds

Clinical Context and Therapy Purpose

The purpose of portable, single-use outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with traumatic and surgical wounds.

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

Populations

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

Interventions

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

Comparators

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

Outcomes

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

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds:[3,]

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

PICO Dressing

Karlakki et al (2016) reported on an RCT with 220 patients that evaluated the use of the PICO device in a surgical center immediately after hip and knee arthroplasties.[36,] The device was left on for 7 days, including the time after the hospital stay. Strengths of the trial included powered intention-to-treat analysis, but evaluators were not blinded. There were trends toward reductions in hospital length of stay (0.9 days; 95% CI, -0.2 to 2.5 days; p=.07) and postoperative surgical wound complications (8.4% control vs. 2.0% PICO, p=.06). However, most of the difference in length of stay was due to wound complications in 2 outliers in the control group (up to 61 days). The level of wound exudate was significantly reduced by the PICO device (p=.007), with 4% of the study group and 16% of the control group having grade 4 (scale grade, 0-4) exudate. Blisters were observed in 11% of patients treated with the PICO system, although the blister occurrence was reported to be reduced when the dressing was stretched less.

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

Prevena System

Pauser et al (2016) reported on a small RCT (n=21) evaluating Prevena in patients who had hemiarthroplasty for femoral neck fractures.[39,] Use of the Prevena System significantly reduced seroma size, days of wound secretion, wound care time, and need for dressing changes. Murphy et al (2019) published findings from the Negative Pressure Wound Therapy Use to Decrease Surgical Nosocomial Events in Colorectal Resections (NEPTUNE) trial, a single-center, superiority-designed, prospective, randomized open-label trial evaluating the use of the Prevena System on closed incisions compared to standard gauze dressings in patients undergoing colorectal resection via laparotomy (N =300).[40,] There was no significant difference in the incidence of SSI at 30 days post-surgery between the Prevena and control groups (32% vs. 34%; p=.68). No significant difference in length of hospital stay was reported.

Hussamy et al (2019) reported on an open-label RCT evaluating the Prevena System for incisional NPWT following cesarean delivery in women with class III obesity (body mass index ≥40; n=222) compared to standard dressings (n=219).[41,] The overall composite wound morbidity rate was not significantly different between the Prevena and control cohorts (17% vs. 19%; RR, 0.9; 95% CI, 0.5 to 1.4).

Tuuli et al (2020) reported on a large, multicenter RCT evaluating the Prevena System for incisional NPWT following cesarean delivery in women with obesity (body mass index >30; n=806) compared to standard dressings (n=802).[42,] The risk of superficial or deep SSI was not significantly different between groups (difference, 0.36%; 95% CI, -1.46% to 2.19%; p=.70). The trial was terminated following a planned interim analysis which indicated an increased rate of adverse events in the Prevena group (difference, 6.95%; 95% CI, 1.86% to 12.03%; p<.001) and futility for the primary outcome.

Bertges et al (2021) conducted a multicenter RCT evaluating the Prevena System for groin incisions in patients undergoing infrainguinal revascularization (n=118) compared to standard dressing (n=124).[43,] The primary composite outcome of groin wound complications, SSI, major noninfectious wound complications, or graft infections within 30 days of surgery was not significantly different between Prevena and control groups (31% vs. 28%; p=.55).

Ceppa et al (2023) conducted a multicenter RCT evaluating the Prevena System (n=82) following major elective colorectal or hepatopancreatobiliary surgery compared to conventional wound therapy (n=82).[44,] The primary endpoint was the rate of postoperative incisional SSIs evaluated at inpatient day 4 or 5 and postoperative day 30; however, results were not stratified by SSI incidence at a specific time point (ie, inpatient vs outpatient occurrence). Results demonstrated that the overall occurrence of the primary endpoint did not significantly differ between the Prevena and conventional therapy groups (14% vs. 17%, respectively; p=.31).

Section Summary: Portable, Single-Use Therapy for Traumatic and Surgical Wounds

The evidence on portable single-use NPWT includes RCTs of the PICO device and RCTs of the Prevena Incision Management System. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use after total joint arthroplasty and 2 single-center RCTs of combined in- and outpatient use after cesarean delivery in women with obesity or other risk factors for poor wound healing. The evidence base for the Prevena System in the outpatient setting is not sufficiently robust for conclusions on efficacy to be drawn. Well-designed comparative studies with larger numbers of patients treated in an outpatient setting are needed.

Supplemental Information

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

2010 Input

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to

guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) 2022 guidelines for prevention of surgical site infections after major extremity trauma included recommendations for NPWT.[45,] The recommendations from AAOS do not support the continued use of NPWT in patients undergoing fracture fixation due to similar outcomes to standard wound care but with an increased healthcare burden. In patients with high-risk surgical incisions, the AAOS recommends that limited evidence suggests NPWT may be an option; however, its use will be influenced by cost. Importantly, these guidelines do not specifically address use in the outpatient setting.

American College of Physicians

In 2015, the American College of Physicians published guidelines (now inactive) on the treatment of pressure ulcers.[46,] The guidelines stated there was low-quality evidence that the overall treatment effect of NPWT did not differ from the standard of care. Of note, the American College of Physicians considers these guidelines inactive since they are more than 5 years old.

Association for the Advancement of Wound Care

In 2010, the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of pressure ulcers. Negative pressure wound therapy was included as a potential second-line intervention if first-line treatments did not result in wound healing (level B evidence). The guidelines indicated that patients must be selected carefully for this procedure. The guidelines were updated in 2014 with additional validation.[47,]

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

International Multidisciplinary Consensus Recommendations

Willy et al (2017) presented evidence-based consensus guidelines on the use of closed incision negative pressure therapy (ciNPT) following surgery.[48,] Among the studies found were 100 randomized controlled studies on ciNPT, most of which found an association between the use of ciNPT and improved outcomes. Based on the evidence, the consensus panel recommended that surgeons evaluate risk in patients before surgery to determine whether patient comorbidities (ie, obesity or diabetes) or the nature of the surgery presents an increased danger of infection. In such cases, the panel recommended the use of ciNPT.

Infectious Diseases Society of America and International Working Group on the Diabetic Foot

A 2023 guideline from the Society for the diagnosis and treatment of diabetic-related foot infections (DFIs) makes the following recommendation relevant to NPWT: "We suggest *not* using the following treatments to address DFIs: (a) adjunctive granulocyte colony-stimulating factor (G-CSF) treatment or (b) topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative-pressure wound therapy (with or without instillation)."[49,] This was graded as a conditional recommendation with low-quality evidence.

National Institute for Health and Care Excellence

In 2013, NICE issued guidance on NPWT for surgical wounds, concluding that "current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen is adequate to support the use of this procedure."[50,]

A 2015 NICE guidance on diabetic foot problems, updated in October 2019, has recommended consideration of NPWT after surgical debridement for diabetic foot ulcers on the advice of the multidisciplinary foot care service.[51,] It was noted that the evidence reviewed for NPWT was limited

and of low quality, and that it would be useful to have more evidence for this commonly used treatment.

In 2014, NICE issued guidance on the prevention and management of pressure ulcers.[52,]The guidance stated, "Do not routinely offer adults negative pressure wound therapy to treat a pressure ulcer, unless it is necessary to reduce the number of dressing changes (for example, in a wound with a large amount of exudate)." Also, the guidance did not recommend NPWT for neonates, infants, or children. A 2019 NICE guidance recommends the use of the PICO7 negative pressure wound dressing for closed surgical incisions due to their association with fewer surgical site infections and seromas compared to standard wound dressings.[53,] The device is considered an option for those who are at high risk for surgical site infections, which may be driven by several factors (eg, age, underlying illness, obesity, smoking, wound classification, and site and complexity of procedure). The device is recommended for those with low to moderate levels of wound exudate who will require infrequent dressing changes.

A 2021 NICE guidance on cesarean birth recommends considering the use of NPWT for women with a body mass index ≥35 kg/m^2 to reduce the risk of wound infections.[54,] Routine use of NPWT following cesarean delivery is not recommended. These recommendations were unchanged in a 2023 update to this guidance.

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

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

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05877378	Efficacy of PICO Single-use System in Chronic Ulcers	42	Apr 2024
NCT05389410	Comparison of Surgical Wound Healing and Complications Following Revision Hip and Knee Replacements, Utilising a 7-day Versus 14-day Negative Pressure Wound Therapy (NPWT) Dressing. A Randomised Controlled Trial	100	Nov 2023
NCT05064696	Prospective Comparison of Wound Complications After Anterior Total Ankle Arthroplasty With and Without PICO Negative Pressure Incisional Dressing	150	Sep 2025
NCT05071443	VACuum-Assisted Closure for Necrotizing Soft Tissue infecTIONs	130	Jun 2025
NCT05266053	Negative Pressure Wound Therapy-PICO: Cosmesis in Repeat C-Sections	100	May 2023
NCT05615844	A Randomized Controlled Trial Comparing Antibiotic Cement Bead Pouch Versus Negative Pressure Wound Therapy for the Management of Severe Open Tibia Fracture Wounds	312	Mar 2025
NCT03414762	PICO Negative Pressure Wound Therapy in Obese Women Undergoing Elective Cesarean Delivery	153	Sep 2022

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03773575[a]	Evaluation of Closed Incision Negative Pressure Dressing (PREVENA) to Prevent Lower Extremity Amputation Wound Complications (PREVENA-AMP)	440	Aug 2024
NCT02682316[a]	A Phase III Randomized Controlled Trial of Negative Pressure Wound Therapy in Post-Operative Incision Management	577	Aprl 2024
NCT04042259	Delayed Primary Closure Using Negative Pressure Wound Therapy	350	Dec 2024
NCT01913132	PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - A Prospective Randomized Trial	644	Dec 2024
NCT02813161	A Real World, Observational Registry of Diabetic Foot Ulcers and Quality of Care in Clinical Practice (DFUR)	10,000	Feb 2025
Unpublished			
NCT04584957	Prophylactic Negative Pressure Wound Therapy in Gynecologic Oncology: a Prospective Controlled Randomized Trial (GO-VAC)	196	Sep 2021
NCT03948412	Negative Pressure Wound Therapy (PREVENA) Versus Standard Dressings for Incision Management After Renal Transplant (IMPART)	500	Sep 2021
NCT02509260	Prevena™ Incisional Negative Pressure Wound Therapy in Re-operative Colorectal Surgery	298	Feb 2021 (completed)
NCT02348034[a]	A Randomized Controlled Trial Exploring the Ability of Negative Pressure Wound Therapy (NPWT) to Reduce Colorectal Surgical Site Infections (SSI)	126	Dec 2020 (completed)
NCT02309944	Negative Pressure Wound Therapy in Obese Gynecologic Oncology Patients	93	June 2020 (completed)
NCT01191567	Negative Pressure Wound Therapy. Therapy Effects and the Impact on the Patient's Quality of Life	200	Terminated
NCT02195310[a]	The Use of Prevena™ Incision Management System on Clean Closed Sternal Midline Incisions in Subjects at High Risk for Surgical Site Occurrences	342	Terminated

NCT: national clinical trial; NR: not reported.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. U.S. Food and Drug Administration. UPDATE on Serious Complications Associated with Negative Pressure Wound Therapy Systems: FDA Safety Communication. 2011 Feb; http://wayback.archive-it.org/7993/20170722215801/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm. Accessed November 11, 2022.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Vacuum-assisted closure in the treatment of chronic wounds. TEC Assessments. 2000;Volume 15:Tab 23.
3. Food and Drug Administration (FDA). Guidance for Industry. Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment. June 2006; https://www.fda.gov/media/71278/download. Accessed November 15, 2023.
4. Rhee SM, Valle MF, Wilson LM, et al. Negative Pressure Wound Therapy Technologies For Chronic Wound Care in the Home Setting. Evidence Report/Technology Assessment (Contract No. 290-201-200007-I) Rockville, MD: Agency for Healthcare Research and Quality; 2014.
5. Rhee SM, Valle MF, Wilson LM, et al. Negative pressure wound therapy technologies for chronic wound care in the home setting: A systematic review. Wound Repair Regen. 2015; 23(4): 506-17. PMID 25845268
6. Sullivan N, Snyder DL, Tipton K, et al. Technology assessment: Negative pressure wound therapy devices (Contract No. 290-2007-10063). Rockville, MD: Agency for Healthcare Research and Quality; 2009.

7. Dumville JC, Hinchliffe RJ, Cullum N, et al. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. Cochrane Database Syst Rev. Oct 17 2013; (10): CD010318. PMID 24132761
8. Liu Z, Dumville JC, Hinchliffe RJ, et al. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. Cochrane Database Syst Rev. Oct 17 2018; 10(10): CD010318. PMID 30328611
9. Wynn M, Freeman S. The efficacy of negative pressure wound therapy for diabetic foot ulcers: A systematised review. J Tissue Viability. Aug 2019; 28(3): 152-160. PMID 31056407
10. Chen L, Zhang S, Da J, et al. A systematic review and meta-analysis of efficacy and safety of negative pressure wound therapy in the treatment of diabetic foot ulcer. Ann Palliat Med. Oct 2021; 10(10): 10830-10839. PMID 34763444
11. Kirsner R, Dove C, Reyzelman A, et al. A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities. Wound Repair Regen. Sep 2019; 27(5): 519-529. PMID 31087729
12. Kirsner RS, Zimnitsky D, Robinson M. A prospective, randomized, controlled clinical study on the effectiveness of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of diabetic ulcers of the lower extremities. Wound Repair Regen. Nov 2021; 29(6): 908-911. PMID 34525239
13. Armstrong DG, Marston WA, Reyzelman AM, et al. Comparison of negative pressure wound therapy with an ultraportable mechanically powered device vs. traditional electrically powered device for the treatment of chronic lower extremity ulcers: a multicenter randomized-controlled trial. Wound Repair Regen. 2011; 19(2): 173-80. PMID 21362084
14. Armstrong DG, Marston WA, Reyzelman AM, et al. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial. Wound Repair Regen. 2012; 20(3): 332-41. PMID 22564228
15. Lerman B, Oldenbrook L, Eichstadt SL, et al. Evaluation of chronic wound treatment with the SNaP wound care system versus modern dressing protocols. Plast Reconstr Surg. Oct 2010; 126(4): 1253-1261. PMID 20885246
16. Shi J, Gao Y, Tian J, et al. Negative pressure wound therapy for treating pressure ulcers. Cochrane Database Syst Rev. May 26 2023; 5(5): CD011334. PMID 37232410
17. Wanner MB, Schwarzl F, Strub B, et al. Vacuum-assisted wound closure for cheaper and more comfortable healing of pressure sores: a prospective study. Scand J Plast Reconstr Surg Hand Surg. 2003; 37(1): 28-33. PMID 12625392
18. Dumville JC, Land L, Evans D, et al. Negative pressure wound therapy for treating leg ulcers. Cochrane Database Syst Rev. Jul 14 2015; 2015(7): CD011354. PMID 26171910
19. Vuerstaek JD, Vainas T, Wuite J, et al. State-of-the-art treatment of chronic leg ulcers: A randomized controlled trial comparing vacuum-assisted closure (V.A.C.) with modern wound dressings. J Vasc Surg. Nov 2006; 44(5): 1029-37; discussion 1038. PMID 17000077
20. Marston WA, Armstrong DG, Reyzelman AM, et al. A Multicenter Randomized Controlled Trial Comparing Treatment of Venous Leg Ulcers Using Mechanically Versus Electrically Powered Negative Pressure Wound Therapy. Adv Wound Care (New Rochelle). Feb 01 2015; 4(2): 75-82. PMID 25713749
21. Dumville JC, Munson C, Christie J. Negative pressure wound therapy for partial-thickness burns. Cochrane Database Syst Rev. Dec 15 2014; 2014(12): CD006215. PMID 25500895
22. Bloemen MC, van der Wal MB, Verhaegen PD, et al. Clinical effectiveness of dermal substitution in burns by topical negative pressure: a multicenter randomized controlled trial. Wound Repair Regen. 2012; 20(6): 797-805. PMID 23110478
23. Krug E, Berg L, Lee C, et al. Evidence-based recommendations for the use of Negative Pressure Wound Therapy in traumatic wounds and reconstructive surgery: steps towards an international consensus. Injury. Feb 2011; 42 Suppl 1: S1-12. PMID 21316515
24. Ehrl D, Heidekrueger PI, Broer PN, et al. Topical Negative Pressure Wound Therapy of Burned Hands: Functional Outcomes. J Burn Care Res. Jan 01 2018; 39(1): 121-128. PMID 28368916

25. Norman G, Shi C, Goh EL, et al. Negative pressure wound therapy for surgical wounds healing by primary closure. Cochrane Database Syst Rev. Apr 26 2022; 4(4): CD009261. PMID 35471497
26. Li HZ, Xu XH, Wang DW, et al. Negative pressure wound therapy for surgical site infections: a systematic review and meta-analysis of randomized controlled trials. Clin Microbiol Infect. Nov 2019; 25(11): 1328-1338. PMID 31220604
27. De Vries FEE, Wallert ED, Solomkin JS, et al. A systematic review and meta-analysis including GRADE qualification of the risk of surgical site infections after prophylactic negative pressure wound therapy compared with conventional dressings in clean and contaminated surgery. Medicine (Baltimore). Sep 2016; 95(36): e4673. PMID 27603360
28. Iheozor-Ejiofor Z, Newton K, Dumville JC, et al. Negative pressure wound therapy for open traumatic wounds. Cochrane Database Syst Rev. Jul 03 2018; 7(7): CD012522. PMID 29969521
29. Stannard JP, Volgas DA, McGwin G, et al. Incisional negative pressure wound therapy after high-risk lower extremity fractures. J Orthop Trauma. Jan 2012; 26(1): 37-42. PMID 21804414
30. Costa ML, Achten J, Bruce J, et al. Effect of Negative Pressure Wound Therapy vs Standard Wound Management on 12-Month Disability Among Adults With Severe Open Fracture of the Lower Limb: The WOLLF Randomized Clinical Trial. JAMA. Jun 12 2018; 319(22): 2280-2288. PMID 29896626
31. Seidel D, Diedrich S, Herrle F, et al. Negative Pressure Wound Therapy vs Conventional Wound Treatment in Subcutaneous Abdominal Wound Healing Impairment: The SAWHI Randomized Clinical Trial. JAMA Surg. Jun 01 2020; 155(6): 469-478. PMID 32293657
32. Stannard JP, Robinson JT, Anderson ER, et al. Negative pressure wound therapy to treat hematomas and surgical incisions following high-energy trauma. J Trauma. Jun 2006; 60(6): 1301-6. PMID 16766975
33. Monsen C, Acosta S, Mani K, et al. A randomised study of NPWT closure versus alginate dressings in peri-vascular groin infections: quality of life, pain and cost. J Wound Care. Jun 2015; 24(6): 252, 254-6, 258-0. PMID 26075373
34. Costa ML, Achten J, Parsons NR. Five-year outcomes for patients sustaining severe fractures of the lower limb : mid-term results from the Wound management for Open Lower Limb Fracture (WOLLF) trial. Bone Joint J. May 2022; 104-B(5): 633-639. PMID 35491582
35. Seidel D, Lefering R. NPWT Resource Use Compared With Conventional Wound Treatment in Subcutaneous Abdominal Wounds With Healing Impairment After Surgery: SAWHI Randomized Clinical Trial Results. Ann Surg. Feb 01 2022; 275(2): e290-e298. PMID 34117147
36. Karlakki SL, Hamad AK, Whittall C, et al. Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: A randomised controlled trial. Bone Joint Res. Aug 2016; 5(8): 328-37. PMID 27496913
37. Peterson AT, Bakaysa SL, Driscoll JM, et al. Randomized controlled trial of single-use negative-pressure wound therapy dressings in morbidly obese patients undergoing cesarean delivery. Am J Obstet Gynecol MFM. Sep 2021; 3(5): 100410. PMID 34058423
38. Gonzalez MG, Barske ME, Kjellsson KB, et al. Topical negative pressure wound therapy to prevent wound complications following caesarean delivery in high-risk obstetric patients: A randomised controlled trial. Aust N Z J Obstet Gynaecol. Aug 2023; 63(4): 516-520. PMID 37140175
39. Pauser J, Nordmeyer M, Biber R, et al. Incisional negative pressure wound therapy after hemiarthroplasty for femoral neck fractures - reduction of wound complications. Int Wound J. Oct 2016; 13(5): 663-7. PMID 25125244
40. Murphy PB, Knowles S, Chadi SA, et al. Negative Pressure Wound Therapy Use to Decrease Surgical Nosocomial Events in Colorectal Resections (NEPTUNE): A Randomized Controlled Trial. Ann Surg. Jul 2019; 270(1): 38-42. PMID 30499799
41. Hussamy DJ, Wortman AC, McIntire DD, et al. Closed Incision Negative Pressure Therapy in Morbidly Obese Women Undergoing Cesarean Delivery: A Randomized Controlled Trial. Obstet Gynecol. Oct 2019; 134(4): 781-789. PMID 31503147

42. Tuuli MG, Liu J, Tita ATN, et al. Effect of Prophylactic Negative Pressure Wound Therapy vs Standard Wound Dressing on Surgical-Site Infection in Obese Women After Cesarean Delivery: A Randomized Clinical Trial. JAMA. Sep 22 2020; 324(12): 1180-1189. PMID 32960242
43. Bertges DJ, Smith L, Scully RE, et al. A multicenter, prospective randomized trial of negative pressure wound therapy for infrainguinal revascularization with a groin incision. J Vasc Surg. Jul 2021; 74(1): 257-267.e1. PMID 33548422
44. Ceppa EP, Kim RC, Niedzwiecki D, et al. Closed Incision Negative Pressure Therapy to Reduce Surgical Site Infection in High-Risk Gastrointestinal Surgery: A Randomized Controlled Trial. J Am Coll Surg. Apr 01 2023; 236(4): 698-708. PMID 36728375
45. American Academy of Orthopaedic Surgeons. Prevention of Surgical Site Infections After Major Extremity Trauma Evidence-Based Clinical Practice Guideline. www.aaos.org/SSItraumacpg. Published 03/21/22. Accessed November 15, 2023.
46. Qaseem A, Humphrey LL, Forciea MA, et al. Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians. Ann Intern Med. Mar 03 2015; 162(5): 370-9. PMID 25732279
47. Association for the Advancement of Wound Care (AAWC). International Consolidated Venous Ulcer Guideline (ICVUG). Update of AAWC Venous Ulcer Guideline, 2005 and 2010. 2015; https://aawconline.memberclicks.net/assets/appendix%20c%20guideline%20icvug-textformatrecommendations-final%20v42%20changessaved18aug17.pdf. Accessed November 16, 2023.
48. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: international multidisciplinary consensus recommendations. Int Wound J. Apr 2017; 14(2): 385-398. PMID 27170231
49. Senneville É, Albalawi Z, van Asten SA, et al. IWGDF/IDSA guidelines on the diagnosis and treatment of diabetes-related foot infections (IWGDF/IDSA 2023). Diabetes Metab Res Rev. Oct 01 2023: e3687. PMID 37779323
50. National Institute for Health and Care Excellence (NICE). Negative Pressure Wound Therapy for the Open Abdomen [IPG467]. 2013; https://www.nice.org.uk/guidance/ipg467. Accessed November 11, 2023.
51. National Institute for Health and Care Excellence (NICE). Diabetic Foot Problems: Prevention and Management [NG19]. Published August 2015; Updated October 2019; https://www.nice.org.uk/guidance/ng19/evidence. Accessed November 14, 2023.
52. National Institute for Health and Care Excellence (NICE). Pressure ulcers: prevention and management [CG179]. 2014; https://www.nice.org.uk/guidance/cg179. Accessed November 10, 2023.
53. National Institute for Health and Care Excellence (NICE). PICO negative pressure wound dressings for closed surgical incisions [MTG43]. 2019; https://www.nice.org.uk/guidance/mtg43. Accessed November 16, 2023.
54. National Institute for Health and Care Excellence (NICE). Cesarean birth [NG192]. Published: March 2021. Updated: September 2023; https://www.nice.org.uk/guidance/ng192. Accessed November 15, 2023.
55. National Institute for Health and Care Excellence (NICE). The VAC Veraflo Therapy system for acute infected or chronic wounds that are failing to heal [MTG54]. 2021; https://www.nice.org.uk/guidance/mtg54. Accessed November 9, 2023.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Prior treatment(s) and response, nutritional status, reason for NPWT, treatment plan including estimated duration of wound VAC therapy

- Current wound evaluation and description including: type, age and size of wound (length, width, and depth), location and amount of drainage
- Operative reports (if applicable)
- Subsequent wound care notes or progress notes including: current treatment, treatment plan, wound measurements, evaluation, progress, and patient compliance. Objective measurements of the wound should include the development and presence of healthy granulation tissue, progressive wound contracture and decreasing depth, and/or the commencement of epithelial spread from the wound margins as applicable.

Post Service (in addition to the above, please include the following):

- Operative report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	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	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
	97607	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
	97608	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
HCPCS	A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
	A7000	Canister, disposable, used with suction pump, each
	A7001	Canister, nondisposable, used with suction pump, each
	A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each

Type	Code	Description
	E2402	Negative pressure wound therapy electrical pump, stationary or portable
	K0743	Suction pump, home model, portable, for use on wounds
	K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq in or less
	K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 sq in but less than or equal to 48 sq in
	K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq in

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/13/2001	BCBSA Medical Policy adoption
11/15/2001	Coverage determination based on external reviews
08/01/2006	Coding Update
10/15/2007	Policy Review
07/01/2011	Policy title change from Vacuum-Assisted Closure (VAC)/Negative Pressure Wound Therapy (NPWT) for Wound Care with position change
03/13/2012	Coding Update
02/22/2013	Coding update and policy guideline clarification
07/03/2014	Coding Update
01/01/2015	Coding Update
04/30/2015	Policy review without position change
07/31/2015	Policy clarification update
04/01/2016	Policy revision without position change
03/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
04/01/2019	Policy revision without position change
03/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2020	Administrative update. Policy statement and guidelines updated.
11/01/2020	Administrative update. Policy statement updated.
03/01/2021	Annual review. Policy statement and literature review updated.
03/01/2022	Annual review. Policy statement, guidelines and literature review updated.
03/01/2023	Annual review. Policy statement, guidelines and literature review updated.
03/01/2024	Annual review. Policy statement, guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent

therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
Initiation of Powered Negative Pressure Wound Therapy I. An initial therapeutic trial of not less than 2 weeks using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling risk factors (e.g., diabetes, nutrition, relief of pressure), may be considered **medically necessary** for **any** of the following: A. Chronic (greater than 90 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care with **any** of the following: 1. High-volume drainage that interferes with healing is present 2. Standard dressings cannot be maintained due to anatomic factor B. Wounds in individuals with underlying clinical conditions that are known to negatively impact wound healing, which are nonhealing (at least 30 days), despite optimal wound care. (Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the NPWT.) C. Traumatic or surgical wounds with **both** of the following: 1. There has been a failure of immediate or delayed primary closure 2. There is documentation of **one or more** of the following: a. Exposed bone within the wound b. Exposed cartilage within the wound c. Exposed tendon within the wound d. Visible foreign material within the wound	**Initiation of Powered Negative Pressure Wound Therapy** I. An initial therapeutic trial of not less than 2 weeks using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling risk factors (e.g., diabetes, nutrition, relief of pressure), may be considered **medically necessary** for **any** of the following: A. Chronic (greater than 90 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care with **any** of the following: 1. High-volume drainage that interferes with healing is present 2. Standard dressings cannot be maintained due to anatomic factor B. Wounds in individuals with underlying clinical conditions that are known to negatively impact wound healing, which are nonhealing (at least 30 days), despite optimal wound care. (Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the NPWT.) C. Traumatic or surgical wounds with **both** of the following: 1. There has been a failure of immediate or delayed primary closure 2. There is documentation of **one or more** of the following: a. Exposed bone within the wound b. Exposed cartilage within the wound c. Exposed tendon within the wound d. Visible foreign material within the wound
Continuation of Powered NPWT II. Continuation of the powered NPWT system, following an initial 2-week therapeutic trial as part of a comprehensive wound care	**Continuation of Powered Negative Pressure Wound Therapy** II. Continuation of the powered NPWT system, following an initial 2-week therapeutic trial as part of a comprehensive wound care

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
program, may be considered **medically necessary** with **all** of the following: A. The treatment trial has resulted in documented objective improvements in the wound(s) B. There will be ongoing objective improvement during subsequent treatment III. The following are considered **investigational**: A. Continuation of the powered NPWT system when the therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound B. Continuation of the powered NPWT system when the wound has developed evidence of wound complications contraindicating continued NPWT C. Continuation of the powered NPWT system when the wound has healed to the extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments D. Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above E. Use of single-use NPWT systems (powered or nonpowered for the treatment of acute or chronic wounds, including but not limited to diabetic, venous, surgical, and traumatic wounds	program, may be considered **medically necessary** with **all** of the following: A. The treatment trial has resulted in documented objective improvements in the wound(s) B. There will be ongoing objective improvement during subsequent treatment III. The following are considered **investigational**: A. Continuation of the powered NPWT system when the therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound B. Continuation of the powered NPWT system when the wound has developed evidence of wound complications contraindicating continued NPWT C. Continuation of the powered NPWT system when the wound has healed to the extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments D. Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above E. Use of single-use NPWT systems (powered or nonpowered for the treatment of acute or chronic wounds, including but not limited to diabetic, venous, surgical, and traumatic wounds