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Negative Pressure Wound Therapy (NPWT) for the Treatment of Wounds

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

Powered Negative Pressure Wound Therapy (NPWT) - Non-Disposable
Electrically powered, non-disposable NPWT as a component of a wound therapy program (see NOTE 1 below*) **may be considered medically necessary** in the following:

A. Acute Wounds (present less than 30 days):

When there is documentation of the need for accelerated formation of granulation tissue not achievable by other topical wound treatments:

- **Traumatic wound**, **OR surgically created wounds** where there has been a failure of immediate or delayed primary closure; OR
- **Ulcers, non-healing wounds, OR complications of surgically created wounds** including but not limited to dehiscence, when the patient has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments, including but not limited to the following examples:
  1. Patient has autoimmune disease, OR
  2. Patient is using prescription transplant rejection drugs, OR
  3. Patient has chronic prescription steroid use; **OR**

B. Chronic Wounds (present at least 30 days):

Chronic non-healing ulcer with lack of improvement for previous 30 days despite standard wound therapy including:

- Application of moist topical dressings,
- Debridement of necrotic tissue (if present),
- Maintenance of adequate nutritional status, AND
- Weekly evaluations with documentation of wound measurements (i.e., length, width, and depth) in one of the following situations:
  1. Chronic Stage 3 or 4 pressure ulcer, OR
  2. Chronic diabetic neuropathic ulcer, OR
  3. Chronic venous or arterial insufficiency ulcer, OR
  4. Chronic ulcer of mixed etiology.

Electrically powered, non-disposable NPWT is contraindicated and therefore **is considered not medically necessary** for the following:

- Necrotic tissue with eschar present; OR
- Untreated osteomyelitis; OR
- Non-enteric and unexplored fistulas; OR
- Malignancy in the wound; OR
- Exposed vasculature; OR
- Exposed nerves; OR
- Exposed anastomotic site; OR
- Exposed organs.

<u>Non-Powered (Mechanical) NPWT - Disposable</u>

Non-powered (mechanical), disposable NPWT systems (e.g., Smart Negative Pressure [SNaP] Wound Care System) for the treatment of acute or chronic wounds **may be considered medically necessary** when meeting **ALL** of the following:

- Meeting either A or B as noted in above criteria; AND
- Exudate no more than 150 cc total in 3 days; AND
- Wound size < 100 cm^2 but larger than 1 cm^2, and < 10 cm in the widest diameter.

Non-Powered (mechanical), disposable NPWT is contraindicated and **therefore considered not medically necessary** for the following:

- The powered NPWT contraindications noted above; OR
- Exposed tendons; OR
- Actively infected wounds; OR
- Inadequately drained wounds; OR
- Actively bleeding wounds.

Non-powered (mechanical), disposable NPWT systems (e.g., Smart Negative Pressure [SNaP] Wound Care System) for the treatment of acute or chronic wounds that do not meet the above criteria **are considered experimental, investigational and/or unproven.**

NOTE 1: NPWT may be considered medically necessary as a component of a wound therapy program for the above ulcers and wounds when a minimum of the following general measures has been considered and applied, OR considered and ruled out prior to application of NPWT:

- Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional; AND
- Application of dressings to maintain a moist wound environment; AND
- Debridement of necrotic tissue if present, without presence of non-explored fistula formation, macroscopic contamination, or presence of malignant cells; AND
- Evaluation of, and provision for, adequate nutritional status; AND
- All underlying medical conditions have been stabilized or are under current management, (e.g., diabetes, venous insufficiency); AND
- Patient compliance with the wound therapy program.

Continuation of NPWT

Continuation beyond the first 30 days and approval for each additional 30-day time period for NPWT for patients who meet initial criteria **may be considered medically necessary** when:

- A licensed medical professional directly assesses the wounds and/or ulcers being treated with NPWT on a regular basis; AND
    1. Supervises or directly performs NPWT dressing changes; and
    2. Documents changes in the dimensions and characteristics of the wounds and/or ulcers at least every two (2) weeks; AND
- The wound/ulcer shows progressive wound healing from month to month.
- Continuation beyond 4 months is requested for extenuating circumstances with clear evidence of benefit; individual consideration may be given based upon submission of clinical documentation as previously outlined.

Continued NPWT **is considered not medically necessary** for wounds and ulcers when:

- The treating physician determines that adequate wound healing has occurred and use of the vacuum system can be discontinued; OR

- Documented quantitative measurements of wound characteristics (including length, width, and depth) have not improved over 30-day period, OR
- Four months have elapsed using a NPWT device (including the time NPWT was applied in an inpatient setting prior to discharge to a lower level of care) in the treatment of any wound.

Powered NPWT – Disposable

Portable, battery powered, disposable NPWT systems (e.g., PICO Single Use Negative Pressure Wound Therapy System, Prevena™ Incision Management System) **are considered experimental, investigational and/or unproven** for all indications.

Other

Use of NPWT **is considered experimental, investigational and/or unproven** in newborns, infants and children (age 12 and below).

Policy Guidelines

None.

Description

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 non-powered (mechanical) NPWT system has also been developed; the Smart Negative Pressure Wound Care System is portable and lightweight (3oz) 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.

Acute wounds
Wounds occur when the integrity of the skin is compromised. Wounds can occur by a fall, a surgery, a tear, piercing, an infectious disease, or by an underlying condition such as diabetes or venous insufficiency causing necrosis of the tissue. The causes may be structural, such as injury, pressure phenomena or physiological. Most acute wounds heal within an expected timeframe, usually within 30 days.

Chronic wounds
Chronic wounds are wounds that do not heal within an expected time frame, usually within 30 days. The most frequently occurring chronic skin wounds are pressure ulcers, venous stasis ulcers, and diabetic foot ulcers.

Pressure Ulcers (Injuries)
In 2016, the National Pressure Ulcer Advisory Panel announced a change in terminology from pressure ulcer to pressure injury and updated the stages of pressure injury. (1) The update includes using the term injury instead of ulcer, Stage 2 definition revised to clarify the difference between moisture-associated skin damage and injury caused by pressure and/or shear; the term suspected was removed from the Deep Tissue Pressure injury diagnostic label; each definition now describes the extent of tissue loss present and the anatomical features that may or may not be present in the stage of injury. The Roman numerals were replaced by Arabic numbers to identify the stages. The update includes the following definitions:
"A pressure injury is a localized damage to the skin and underlying tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue."

<u>Pressure Injury Stages</u>
Stage 1 Pressure injury: Non-blanchable erythema of intact skin
Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis
Partial thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD),

medical adhesive related skin injury (MARSI), or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Injury: Full-thickness skin loss
Full thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an unstageable pressure injury.

Stage 4 Pressure Injury: Full-thickness skin and tissue loss
Full thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage, or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an unstageable pressure injury.

Additional Categories /Stages:
Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss
Full thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e., dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

Deep Tissue Pressure Injury: Persistent non-blanchable deep red, maroon or purple discoloration
Intact or nonintact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration, or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle, or other underlying structures are visible, this indicates a full-thickness pressure injury (unstageable, Stage 3, or Stage 4). Do not use deep tissue pressure injury to describe vascular, traumatic, neuropathic, or dermatologic conditions.

The focus of this medical policy is the use of NPWT in the outpatient setting. It is recognized that patients may begin using the device in the inpatient setting as they transition to the outpatient setting.

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

NPWT NP32 Device (Foryou Medical Electronics), SVED® (Cardinal Health), and PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew).

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

A non-powered 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.

NPWT 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. (2) This FDA alert noted contraindications to the use of NPWT systems which include the following conditions: necrotic tissue with eschar present, untreated osteomyelitis, non-enteric and unexplored fistulas, malignancy in the wound, exposed vasculature, exposed nerves, exposed anastomotic site, and exposed organs. (2, 3)

FDA product code: OMP.

Table 1. FDA approved negative pressure wound therapy devices. (3, 4) (*NOTE: This is not an all-inclusive list. Refer to the FDA web site at www.fda.gov for additional information on devices.)

Device Name	Premarket Notification (510(k))	Regulation Name
Powered Negative Pressure Wound Therapy (NPWT) - Non-Disposable		

V.A.C. ULTA™ Negative Pressure Wound Therapy System (KCI USA, INC.)	K162790 K100657	Powered Suction Pump
V.A.C. ® Therapy System, ActiV.A.C.® Therapy Unit, InfoV.A.C.®, V.A.C. Freedom®, and Simplicity™ Negative Pressure Wound Therapy Systems (KCI USA, INC.)	K062227 K120033 K063692 K063740 K201571	Powered Suction Pump
V.A.C.® Freedom™ V.A.C. ® ATS™	K032310	Powered Suction Pump
Versatile 1 EZCare™ (BlueSky Medical Group, Inc.)	K061919	Powered Suction Pump
Versatile 1™ (BlueSky Medical Group, Inc.)	K042134	Powered Suction Pump
RENASYS™ GO Negative Pressure Wound Therapy Device (Smith & Nephew, Inc.)	K152163, K083375	Powered Suction Pump
RENASYS™ EZ PLUS (Smith & Nephew, Inc.)	K151326	Powered Suction Pump
RENASYS™ TOUCH Negative Pressure Wound Therapy Device (Smith & Nephew, Inc.)	K153209	Powered Suction Pump
RENASYS™ EZ MAX Negative Pressure Wound Therapy Device (Smith & Nephew, Inc.)	K142979	Powered Suction Pump
Genadyne A4-XLR8 Wound Vacuum System (Genadyne Biotechnologies Inc.)	K090638	Powered Suction Pump
Medela® Invia Liberty Negative Pressure Wound Therapy System (Medela AG)	K142626	Powered Suction Pump
Medela® Invia Wound Therapy (Medela AG)	K080357	Powered Suction Pump
ABThera™ (KCI USA, INC.)	K120499	Powered Suction Pump
VAC Rx4 Negative Pressure Wound Therapy System (KCI USA, INC.)	K160487	Powered Suction Pump
extriCARE® 2400 Negative Pressure Wound Therapy System (Devon Medical Products, Inc.)	K110078	Powered Suction Pump
Foryou NPWT NP32 Device (Foryou Medical Electronics Co., Ltd.)	K113236	Powered Suction Pump
ANTLIA II™ Suction Pump System (Innovative Therapies, Inc.)	K070904 K111333	Powered Suction Pump
Vacuum Assisted Closure® (KCI USA, INC.)	K021500	Powered Suction Pump
Non-Powered (Mechanical) NPWT - Disposable		
SNaP® Wound Care System (Spiracur Inc.)	K151710 K113032 K112341 K111393 K084106	Non-powered suction apparatus device intended for negative pressure wound therapy
Powered NPWT – Disposable		

PICO™ Single Use Negative Pressure Wound Therapy System (Smith & Nephew, Inc.) PICO 7 Single Use Negative Pressure Wound Therapy System, PICO 7Y Single Use Negative Pressure Wound Therapy System, PICO 14 Single Use Negative Pressure Wound Therapy System (Smith & Nephew, Medical Limited)	K151436 K112127 K111170 K202157	Powered Suction Pump
Prevena™ Incision Management System (KCI USA, INC.) PREVENA PLUS Incision Management System (No Ag), PREVENA PLUS DUO Incision Management System (No Ag) (KCI USA, INC.)	K133232 K190697	Powered Suction Pump
V.A.C. Via™ Negative Pressure Wound Therapy System (KCI USA, INC.)	K132741 K093526	Powered Suction Pump

Rationale

This medical policy was developed in August 1998 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through November 11, 2023.

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

NPWT devices are classified as either powered (i.e., requiring an electrical power source or batteries) or non-powered (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: (6)

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

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 (AHRQ) 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. (7) There were 3 retrospective cohort studies on diabetic foot ulcers and arterial ulcers, an RCT and two retrospective cohort studies on pressure ulcers, and a retrospective cohort on venous ulcers. Six studies used the V.A.C. and the other used the Smart Negative Pressure (SNaP) Wound Care System device. Reviewers found that interpretation of available data was limited by variability in the types of comparator groups, methodologic limitations, and poor reporting of outcomes. (8)

Another AHRQ 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. (9)

Diabetic Lower-Extremity Ulcers and Amputation Wounds

Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this medical policy.

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

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. (6)

- 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.

Systematic Reviews
A 2013 Cochrane review of NPWT for treating foot wounds in patients with diabetes (10) was updated in 2018 to include 11 RCTs (N=972) with sample sizes ranging from 15 to 341 participants. (11) 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 (relative risk [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. (12) However, reviewers emphasized limitations in the present body of evidence, including methodological flaws such as the absence of validated tools for the measurement of wound depth and area, lack of statistical power calculations, and heterogeneity in pressure settings employed during therapy.

A 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. (13) 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 patients with diabetic lower-extremity ulcers or amputation wounds.

The following PICO was used to select literature to inform this medical policy.

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

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: (6)

- 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.

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 (VLU; n=104) or diabetic foot ulcers (DFU; n=60) to treatment with PICO single-use NPWT (s-NPWT; n=80) or traditional, reusable NPWT systems (t-NPWT; n=84). (14) 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 (ITT) analysis. For the per protocol (PP) analysis, 16 (20%) and 30 (37%) patients were excluded from the s-NPWT and t-NPWT arms, respectively. Randomization was stratified by wound type and wound size. The PICO dressing was set to provide -80 mmHg of negative pressure. Choice of traditional, NPWT device

manufacturer and pressure setting was at the discretion of the treating physician, with an average pressure of -118.3 mmHg (median, -125 mmHg; SD, 23.4 mmHg) applied.

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

Confirmed wound closure (ITT) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted odds ratio of 0.294 (95% CI, 0.135 to 0.638; p=.002) for all wound types and 0.161 (95% CI, 0.035 to 0.744; p=.020) for DFU. However, the subgroup analysis for DFU patients in the PP population was not significant.

The median estimate of the time to achieve confirmed closure was 77 days for s-NPWT (95% CI, 49 to undefined limit) and could not be calculated for t-NPWT due to the low number of patients achieving this endpoint. No significant differences were noted in health-related quality of life between baseline and exit visits. Fifty-seven treatment-related adverse events were reported, 16 related to s-NPWT in 12 patients and 41 related to t-NPWT in 29 patients. Wound-related adverse events included increase in target ulcer size, inability to tolerate NPWT, and periwound skin maceration, resulting in study discontinuation by 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 DFU.

A subanalysis of this RCT highlighting outcomes in patients with lower-extremity (foot and venous leg) diabetic ulcers was published by Kirsner and colleagues. (15) 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, non-powered (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 results of a planned interim analysis of an RCT comparing the SNaP Wound Care System with the Vacuum Assisted Closure (V.A.C.) Therapy for the treatment of chronic lower-extremity wounds. (16) Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012. (17) 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. (18) 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 non-powered 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. These studies are insufficient to draw conclusions about the impact of single-use NPWT devices on the net health outcome compared with current care.

Chronic Pressure Ulcers

Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this medical policy.

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, quality of life, 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: (6)

- 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.

Systematic Reviews

A 2015 Cochrane review included 4 RCTs of NPWT (N=149 patients) for treating pressure ulcers in any care setting, although most of the patients were treated in a hospital setting. (19) 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.

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. (20) 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 versus 28 days in the control group). Findings were limited by the small number of patients in the study, the possibility that the control group might not have received optimal wound management, and lack of information on the time to complete wound healing.

Section Summary: Chronic Pressure Ulcers

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

Lower-Extremity Ulcers due to Venous Insufficiency

Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this medical policy.

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, quality of life, 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: (6)

- 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.

Randomized Controlled Trials

A 2015 Cochrane review of NPWT for venous insufficiency identified a single RCT with 60 patients. (21) 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. (22) 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 use of NPWT for the treatment of lower-extremity ulcers due to venous insufficiency in the hospital setting. No evidence was identified on treatment in the home setting.

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

Clinical Context and Therapy Purpose

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

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

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, quality of life, 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: (6)

- 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.

PICO Dressing

Kirsner et al. (2019) published an RCT that allocated 164 patients with venous leg ulcers (VLU; n=104) or diabetic foot ulcers (DFU; n=60) to treatment with PICO single-use NPWT (s-NPWT; n=80) or traditional, reusable NPWT systems (t-NPWT; n=84). (14) 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% versus 69.9%; p=.003) in the per protocol (PP) analysis and 39.1% (90.24% versus 51%; p<.001) in the intention-to-treat (ITT) analysis. This treatment effect was also significant in the VLU subgroup (p=.007). However, confidence intervals were not reported. Confirmed wound closure (ITT) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted odds ratio of 0.294 (95% CI, 0.135 to 0.638; p=.002) for all wound types and 0.398 (95% CI, 0.152 to 1.044; p=.061) for VLU. The subgroup analysis for VLU patients in the PP 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. (16) Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012. (17) 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). (23) However, this study had a high loss to follow-up and lacked a comparison with standard treatment protocols.

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

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

The following PICO was used to select literature to inform this medical policy.

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, quality of life, 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: (6)
- 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.

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. (24) 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. (25) 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. (26)

Case Series

A retrospective case series by Ehrl et al. (2017) examined outcomes for 51 patients treated for burned hands with topical negative pressure wound (TNPW) therapy at a single-center; of the initial 51 patients, only 30 patients (47 hands) completed follow-up, which was conducted an average of 35 months after injury and included physical examination. (27) Before TNPW therapy, patients received escharotomy or superficial debridement if needed, or split-thickness skin grafts for third-degree burns and the TNPW gloves used allowed caregivers to assess patients' fingertips for perfusion. Ergotherapy was initiated following evidence of epithelialization. Primary endpoints were a dorsal extension of the fingers and capability of complete active fist closure, with the majority of patients achieving 1 or both outcomes: the first end point was reached in 85.1% (n=40) of the cases; the second end point 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 TNPW therapy as standard treatment at the institution from which these data were drawn.

Section Summary: Burn Wounds
The evidence on NPWT as a primary treatment of partial-thickness burns is limited. A retrospective case series reported 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 patients with traumatic or surgical wounds.

The following PICO was used to select literature to inform this medical policy.

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, quality of life, 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: (6)
- 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.

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.

Systematic Reviews

Selected systematic reviews and meta-analyses evaluating the use of NPWT in surgical and/or traumatic wounds are summarized in Table 2.

Table 2. 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) (28)	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) (29)	45	0	Adult surgical patients	6624 (30 to 876)	SSIs were significantly lower; all other outcomes NSD	Certainty of the pooled effect	Studies generally included devices of

						ranked as low due to serious risk of bias	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) (30)	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) (31)	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. (28) 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; I2=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) were conducted comparing the effectiveness and safety of NPWT with standard surgical dressing or conventional therapy for prevention of SSI. (29) 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; I2=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; I2=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 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 surgical site infections after prophylactic NPWT. (30) 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 use of NPWT reduced the rate of surgical site infections (odds ratio, 0.56; 95% CI, 0.32 to 0.96; p=.04) and reduced the surgical site infection rate from 140 to 83 per 1000 patients. However, the quality of evidence was rated as low due to high-risk of bias in the nonblinded assessments and imprecision in the estimates. Subgroup meta-analysis of 4 RCTs in orthopedic/trauma surgery did not demonstrate significant benefit in regards to reducing risk of SSI (OR 0.58; 95% CI, 0.32 to 1.07).

A 2018 Cochrane review evaluated the effects of NPWT for open traumatic wounds (e.g., open fractures or soft tissue wounds) managed in any care setting. (31) 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 for wound infection risk (RR 0.44; 95% CI, 0.17 to 1.10). One study comparing NPWT at 125 mmHg against 75 mmHg in other open traumatic wounds also failed to demonstrate a significant difference in wound infection risk (RR 1.04; 95% CI, 0.31 to 3.51). Evidence was deemed low to very low in certainty and quality due to imprecision and risk of bias.

Randomized Controlled Trials

Selected RCTs of NPWT for surgical or traumatic wounds are summarized in Table 3.

Table 3. Summary of Key RCTs of NPWT versus Standard Therapy in Surgical Wounds

Study; Trial	Surgery Received	Number of Participants	Notes on NPWT effectiveness	P- value
Stannard et al. (2012) (32)	Various, after fractures and other trauma	249	Fewer infections, less discharge than standard closure	.049
Costa et al. (2018); WOLLF (33)	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 et al. (2020); SAWHI (34)	Subcutaneous abdominal wound healing impairment	539 (randomized) 507 (modified intention-to-treat) 310 (per protocol)	Shorter time to wound closure and higher wound closure rate	<.001

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

One of the largest studies on prophylactic NPWT for surgical wounds is a report from an investigator-initiated, industry- sponsored multicenter RCT of inpatient NPWT for closed surgical incisions by Stannard et al. (2012) (32). (A preliminary report was published in 2006). (35) 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 quality of life improvements compared with standard wound care. (36)

The Effect of Negative Pressure Wound Therapy versus 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). (33) 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 versus 42.4; p=.13), in the number of deep infections (16 [7.1%] versus 19 [8.1%]; p=.64), or in quality of life 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. (37) 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). (34) The modified ITT population included 256 and 251 patients assigned to NPWT and CWT, respectively. The primary outcome, mean time to wound closure within 42 days, was significantly shorter in the NPWT group (difference, 3.0 d; 95% CI, 1.6 to 4.4; P<.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 PP analysis, however, 39% and 31% of patients were excluded from the NPWT and CWT arms, respectively. Primary reasons for exclusion included unauthorized treatment crossovers, insufficient dressing changes, and treatment termination prior to 42 days. More wounds were sutured in the NPWT arm compared to the CWT arm, where more wounds healed by secondary intention. No significant differences were noted for quality of life or pain measures at any time point. The relative risk for adverse events (RR, 1.20; 95% CI, 0.97 to 1.47) and wound-related adverse events (RR, 1.51; 95% CI, 0.99 to 2.35) was higher in the NPWT arm. The most frequently documented wound-related adverse events in the NPWT arm included periwound macerations and local infections with signs of inflammation. Overall, it is unclear if a 3-day difference in time to wound closure represents a clinically meaningful benefit. Time to hospital discharge, readmission rates, and duration of outpatient care were not reported; however, in an analysis of resource use, hospitalization time was longer with NPWT than CWT (11.8 days versus 13.9 days). (38) Time for dressing changes (196 versus 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 patients with traumatic and surgical wounds.

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

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, quality of life, 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: (6)

- 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.

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. 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. (39) 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 versus 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). (40) 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.

Prevena System

Pauser et al. (2016) reported on a small RCT (n=21) evaluating Prevena in patients who had hemiarthroplasty for femoral neck fractures. (41) 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). (42) There was no significant difference in the incidence of SSI at 30 days post-surgery between the Prevena and control groups (32% versus 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). (43) The overall composite wound morbidity rate was not significantly different between the Prevena and control cohorts (17% versus 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). (44) 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). (45) 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% versus 28%; p=.55).

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 a single-center RCT of combined in- and outpatient use after cesarean delivery in obese women. The evidence base for the Prevena System is not sufficiently robust for conclusions on efficacy to be drawn. Well-designed comparative studies with larger numbers of patients treated in an outpatient setting are needed.

In addition to the literature mentioned above, clinical trials were reviewed that included the following limitations: small sample size studies, heterogeneous patient populations, and lack of standard wound care criteria. One study which looked at outpatient wounds concluded that larger size clinical trials were needed to evaluate the benefit. (57-69)

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

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. In this study, the PICO device demonstrated noninferiority for wound area reduction. A statistically significant benefit in complete wound closure was noted for patients with diabetic foot ulcers (DFUs) but was not duplicated in the per protocol population due to a high number of exclusions. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

For individuals who have lower-extremity ulcers due to venous insufficiency who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. In this study, the PICO device demonstrated noninferiority for wound area reduction. No significant benefit in complete wound closure was found in patients with venous ulcers. One study of the SNaP™ System showed noninferiority to a V.A.C. device for wound size reduction. A subgroup analysis of this study found a significant difference in complete wound closure for patients with venous ulcers. However, interpretation of this study is limited by a high loss to follow-up and lack of a control group treated with standard dressings. Well-designed comparative studies with larger numbers of patients powered to detect differences in complete wound closure are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have traumatic or surgical wounds who receive NPWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Systematic reviews of RCTs in patients with surgical wounds have generally found lower risk of surgical site infection (SSI); however, many studies are limited to short-term use of NPWT limiting applicability to the outpatient setting. For patients with traumatic wounds, a Cochrane review failed to find significant improvement in patients treated with NPWT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

Practice Guidelines and Position Statements

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. (46) 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 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.

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. (47) 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 (i.e., obesity or diabetes) or the nature of the surgery presents an increased danger of infection. In such cases, the panel recommended the use of ciNPT.

Infectious Diseases Society of America and Surgical Infection Society

The 2012 (update in development) guidelines from the Society for the diagnosis and treatment of diabetic foot infections stated that no adjunctive therapy has been proven to improve the resolution of infection, but for select diabetic foot wounds that are slow to heal, clinicians might consider using NPWT (weak recommendation, low-quality evidence). (48)

American College of Physicians

In 2015, the American College of Physicians (ACP) published guidelines (now inactive) on the treatment of pressure ulcers. (49) The guidelines stated there was low-quality evidence that the overall treatment effect of NPWT did not differ from the standard of care.

Association for the Advancement of Wound Care

In 2010, the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of pressure ulcers. 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. (50)

In 2010, the AAWC published guidelines on the care of venous ulcers. (50) 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.

National Institute for Health and Care Excellence

In 2013, the National Institute for Health and Care Excellence (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.” (51)

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. (52) 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. (53) 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. (54) The device is considered an option for those who are at high risk for surgical site infections, which may be driven by several factors (e.g., 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.

An updated 2023 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. (55) Routine use of NPWT following cesarean delivery is not recommended.

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. (56) 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.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 5.

Table 5. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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	312	Mar 2025

	Pressure Wound Therapy for the Management of Severe Open Tibia Fracture Wounds		
NCT03414762	PICO Negative Pressure Wound Therapy in Obese Women Undergoing Elective Cesarean Delivery	153	Sep 2022
NCT03773575[a]	Evaluation of Closed Incision Negative Pressure Dressing (PREVENA) to Prevent Lower Extremity Amputation Wound Complications (PREVENA-AMP)	440	Dec 2023
NCT02682316[a]	A phase III Randomized Controlled Trial of Negative Pressure Wound Therapy in Post-Operative Incision Management	577	Feb 2022 (ongoing)
NCT04042259	Delayed Primary Closure Using Negative Pressure Wound Therapy	350	Dec 2022
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)
NCT02799667	Randomized Controlled Trial: Do Single Use Negative Pressure Dressings Reduce Wound Complications in Women With a BMI >40kg/m^2 Undergoing Cesarean Delivery at a Tertiary Medical Center?	110	Terminated
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; No.: Number; NR: not reported
[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97605, 97606, 97607, 97608
HCPCS Codes	A6550, A7000, A7001, A9272, E2402, K0743, K0744, K0745, K0746

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
08/15/2024	Reviewed. No changes.
12/01/2023	Document updated with literature review. Coverage unchanged. References 3, 11, 13, 15, 28, 37-38, 40, 44-46, and 55-56 added; some updated and others removed.
08/15/2022	Reviewed. No changes.
08/01/2021	Document updated with literature review. Coverage unchanged. References 6, 10, 11, 13, 14, 32, 33, 40, 46, 47, and 58 were added and some references were removed.
08/15/2020	Reviewed. No changes.
12/01/2019	Document updated with literature review. Coverage unchanged. References 11, 19, 29-33, 40, 44, 53-66 were added and some removed.

02/15/2018	Document updated with literature review. The following changes were made: Coverage section: 1) Coverage divided into 4 sections that include Powered Negative Pressure Wound Therapy (NPWT) – Non-Disposable, Non-powered (Mechanical) NPWT – Disposable, Powered NPWT – Disposable and Other, and 2) Modified exudate and wound size criteria for non-powered (mechanical) disposable NPWT systems, and 3) An EIU statement was added for Powered NPWT – Disposable.
06/01/2016	Reviewed. No changes.
08/15/2015	Document updated with literature review. The following changes have been made to the Coverage section: 1) The following statement was removed: There is no clinical documentation of wound healing to support the continued use of a NPWT device. 2). The following bullet was added to the "Continued powered and non-powered NPWT" is considered not medically necessary statement: Four months have elapsed using a NPWT device (including the time NPWT was applied in an inpatient setting prior to discharge to a lower level of care) in the treatment of any wound. 3) The "Continuation beyond the first 30 days" may be considered medically necessary statement was clarified to: "Continuation beyond the first 30 days and approval for each additional 30 days' time period for a powered and non-powered NPWT for patients who meet initial criteria may be considered medically necessary when; …" 4) An additional bullet was added to this section: "The continuation beyond 4 months is requested for extenuating circumstances with clear evidence of benefit; individual consideration may be given based upon submission of clinical documentation as previously outlined." 5) The following "Acute wounds (present less than 30 days)": section was clarified to the following: Traumatic wound, OR surgically created wounds where there has been a failure of immediate or delayed primary closure; OR ulcers, non-healing wounds, OR complications of surgically created wounds including but not limited to dehiscence.
08/15/2014	Document updated with literature review. The following coverage changes were made: Non-powered negative pressure wound therapy (NPWT) may be considered medically necessary when meeting conditional criteria. Non-powered NPWT systems (e.g., Smart Negative Pressure [SNaP] Wound Care System) for the treatment of acute or chronic wounds that do not meet the criteria are considered experimental, investigational and/or unproven.
11/01/2013	Document updated with literature review. The following coverage changes were made: 1) In section A. Acute Wounds (present less than 30 days): under Ulcers, non-healing wounds, complications of a surgically created wound, wording changed from "in one of the following situations" to "including but not limited to the following examples" 2) "NPWT is considered not medically necessary for:" changed to "NPWT is contraindicated and therefore is considered not medically necessary for:" 3) The following were added to the list of indications for which NPWT is considered not medically necessary: Non-enteric and unexplored fistulas; or Exposed vasculature; or Exposed

	nerves; or Exposed anastomotic site; or Exposed organs. 4) The following was added: Use of NPWT is considered experimental, investigational and unproven in newborns, infants and children (age 12 and below).
01/01/2012	Document updated with literature review. The following changes were made: 1) Coverage section now differentiates between powered and non-powered devices 2) Use of non-powered NPWT systems (e.g., Smart Negative Pressure [SNaP] Wound Care System) for the treatment of acute or chronic wounds is considered experimental, investigational and unproven. Title changed: VAC or Versatile 1 was removed. CPT/HCPCS code(s) updated.
08/01/2011	CPT/HCPCS code(s) updated.
02/15/2010	Policy updated with literature review. The following change was made: NPWT may be considered medically necessary for certain wounds that are less than 30 days old when criteria are met.
04/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
10/01/2006	Revised/updated entire document
07/01/2004	Revised/updated entire document
11/01/2000	Revised/updated entire document
04/01/1999	Revised/updated entire document
08/01/1998	New medical document