Medical Coverage Policy

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Negative Pressure Wound Therapy/Vacuum Assisted Closure (VAC) for Nonhealing Wounds

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Overview

This Coverage Policy addresses the use of disposable non-powered mechanical and disposable single use battery-powered negative pressure wound therapy (NPWT)/vacuum-assisted closure (VAC) for a variety of nonhealing wounds. NPWT is intended to be used in hospitals, clinics, long term care and home care settings. These devices can be distinguished from one another by criteria such as whether they are portable or fixed, operate electrically or mechanically, and whether they are reusable or disposable.

Coverage Policy

Coverage for Durable Medical Equipment (DME) including negative pressure wound therapy/vacuum-assisted closure devices and accessories varies across plans. Refer to the customer's benefit plan document for coverage details.

Each of the following disposable negative pressure wound therapy (NPWT) and vacuum assisted closure (VAC) devices is not covered or reimbursable for ANY indication:

- non-powered mechanical (e.g., Smart Negative Pressure [SNaP®] Wound Care Device) (CPT codes 97607, 97608, HCPCS code A9272)
- single use battery-powered (e.g., PICO Single Use Negative Pressure Wound Therapy System, Prevena Incision Management System, V.A.C. Via Negative Pressure Wound Therapy System, MyNeWT Negative Pressure Wound Therapy System, Uno Negative Pressure Wound Therapy System) (CPT codes 97607, 97608, HCPCS code A9272)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Not Covered or Reimbursable:

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

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

HCPCS Codes	Description
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each

General Background

Chronic wounds, also known as ulcers, are wounds that have not completed the healing process in the expected time period, usually 30 days, or have proceeded through the healing phase without establishing the expected functional results. These wounds generally do not heal without intervention and are sometimes unresponsive to conventional therapies. Neuropathic diabetic foot ulcers, pressure ulcers, venous leg ulcers, and arterial ulcers are examples of chronic wounds.

Numerous treatments have been proposed to treat chronic wounds including ultrasound, laser, electromagnetic therapy (EM), electrical stimulation (ES), hyperbaric oxygen, gene therapy, surgical debridement, surgical revascularization of the affected area, myocutaneous skin flaps or grafting, wet-to-dry dressings, negative pressure wound therapy, vacuum-assisted closure, negative pressure wound therapy with wound instillation (NPWTi), and the use of certain bioengineered skin substitutes. When clinically appropriate, these interventions may be used in combination with medical management of the underlying wound etiology.

Negative Pressure Wound Therapy (NPWT) or Vacuum-Assisted Closure (VAC):
NPWT or VAC is intended to be used in hospitals, clinics, long term care and home care settings. NPWT involves application of a localized vacuum to draw the edges of the wound together and enhance new growth while providing a moist environment conducive to rapid wound healing. Negative pressure is produced in the wound bed by placing a dressing (i.e., open-celled reticulated foam or moistened gauze) in the wound and sealing the dressing to the skin with a transparent adhesive film dressing. A tube embedded in the dressing connects to a vacuum pump to produce sub atmospheric pressure and drain off wound exudate. The vacuum pump provides either continuous or intermittent negative pressure, adjusted for the type of wound. Pressure is applied in the range of 5 to 125 mmHg (adjustable to higher pressures, depending on the device used). Manufacturers recommend changing the dressing at 48 hours, then two to three times per week as indicated. Depending on the type of NPWT or VAC used, the power source can be either electrically powered via AC outlet and/or rechargeable battery, mechanical energy using a spring/coil or elastomeric mechanism, or with an internal disposable battery (Kuplicki, 2016).

This technology is primarily intended for chronic wounds that have not healed when treated with other forms of wound care and for minimizing scarring on acute wounds by promoting healing through granulation tissue formation and re-epithelization. NPWT may be either a primary or secondary line of treatment, depending on the type of wound.

NPWT with instillation (NPWTi), a novel treatment, involves the use of open-cell foam sponge for periodic instillation of the wound bed with sterile fluid. This facilitates removal of thick exudate and infectious materials. The duration as well as time interval between each instillation can be adjusted based on the requirements of the wound. Different solutions have been used for instillation, including normal saline and dilute Dakin solution (Stefanos et al., 2022).

Powered NPWT/VAC: A powered NPWT/VAC is typically used to treat large, deep, complex, or heavily exudating wounds in a hospital, long-term care, skilled nursing, or a home health setting and can be used for weeks to months. They are electrically powered with an AC outlet and/or rechargeable battery. Negative pressure is generated with an electric vacuum pump that creates and regulates suction. Pressure settings are adjustable and can be continuous and/or intermittent. An external canister, suitable for moderate to heavy exudate, is used to manage exudate (Kuplicki, 2016).

Disposable Non-Powered Mechanical or Single Use Battery-Powered NPWT/VAC: Smaller disposable non-powered or single use battery-powered NPWT devices have been proposed for the treatment of smaller wounds or on closed incisions after surgery to prevent potentially surgical site infections and other wound complications in high-risk patients. They can be used for short-term, single-course therapy for a fixed duration typically 7-14 days depending on the device. They either use mechanical energy with a spring/coil or elastomeric mechanism or have an internal disposable battery to generate negative pressure. The pressure settings are preset, continuous, fixed, and have limited or no adjustability. Disposable non-powered mechanical NPWT/VACs are usually canister free leaving exudate to absorb into the dressing. Single use devices are often canister-free or have a very small internal reservoir designed for low exudate volumes. These devices are used in the hospital, outpatient and/or home settings (Kuplicki, 2016; Dohmen, et al., 2014; Hudson, et al., 2013; Fong and Marston, 2012; Lerman, et al., 2010b).

U.S. Food and Drug Administration (FDA)

In February 2011, the FDA issued an FDA Safety Communication: Update on serious complications associated with negative pressure wound systems. The FDA issued the alert to make individuals aware of deaths and serious complications, especially bleeding and infection, associated with the use of Negative Pressure Wound Therapy (NPWT) systems, and to provide recommendations to reduce the risk. Although rare, these complications can occur wherever NPWT systems are used, including acute and long-term healthcare facilities and at home. Bleeding continues to be the cause of the most serious adverse events (FDA, 2013).

The safety and effectiveness of NPWT systems in newborns, infants and children has not been established at this time and currently, there are no NPWT systems cleared for use in these populations (FDA, 2013).

The FDA recommends selecting patients for NPWT carefully, after reviewing the most recent device labeling and instructions and that the patient is monitored frequently in an appropriate care setting by a trained practitioner. In determining the frequency of monitoring, consider the patient’s condition, including the wound status, wound location and co-morbidities. The FDA recommends numerous patient risk factors/characteristics to consider before NPWT use**.** The FDA recommends that NPWT is contraindicated for these wound types/conditions:

- necrotic tissue with eschar present
- untreated osteomyelitis
- non-enteric and unexplored fistulas
- malignancy in the wound
- exposed vasculature
- exposed nerves
- exposed anastomotic site
- exposed organs

Patient risk factors/characteristics to consider before NPWT use:

- patients at high risk for bleeding and hemorrhage
- patients on anticoagulants or platelet aggregation inhibitors
- patients with:
  - friable vessels and infected blood vessels
  - vascular anastomosis
  - infected wounds
  - osteomyelitis
  - exposed organs, vessels, nerves, tendons, and ligaments
  - sharp edges in the wound (i.e., bone fragments)
  - spinal cord injury (stimulation of sympathetic nervous system)
  - enteric fistulas
- patients requiring:
  - MRI
  - Hyperbaric chamber
  - Defibrillation
- patient size and weight
- use near vagus nerve (bradycardia)
- circumferential dressing application
- mode of therapy- intermittent versus continuous negative pressure

Disposable Non-Powered Mechanical or Single Use Battery-Powered NPWT/VAC:

Across multiple disposable negative pressure wound therapy (NPWT) and vacuum-assisted closure systems the FDA has granted Class II clearance through the 510(k) regulatory pathway, with substantial equivalence commonly claimed to earlier NPWT predicate devices. As described in the clearance summaries, these devices share common indications for use in wound management via the application of negative pressure to remove low to moderate levels of wound exudate and infectious materials and to promote wound healing, including use in a range of wound types such as chronic, acute, traumatic, subacute, and dehisced wounds; partial-thickness burns; ulcers (e.g., diabetic or pressure); flaps and grafts, and, for some systems, closed or draining surgical incisions, across hospital, extended, and home care settings (FDA, 2026).

Device or Product	Identifier	Manufacturer
MyNeWT Negative Pressure Wound Therapy System	K161432	Stortford Medical LLC
PICO Single Use Negative Pressure Wound Therapy System	K112127	Smith and Nephew, Inc.
PICO 7Y Single Use Negative Pressure Wound Therapy System	K182323	Smith & Nephew Medical Limited
Prevena Incision Management System	K100821	KCI USA, Inc.
SNaP® Wound Care System	K111393	Spiracur, Inc.
Uno Negative Pressure Wound Therapy System	K161599	Genadyne Biotechnologies, Inc.

*FDA product codes: OMP, OKO

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review:

The available studies in the peer-reviewed scientific literature addressing disposable non-powered mechanical or single use battery-powered NPWT fail to establish the intervention as superior to standard treatment options (e.g., standard wound dressings). The literature is generally limited by small sample size and lack of a comparator and therefore conclusions about the safety, efficacy and health outcomes cannot be made at this time. Additionally, many of the studies report that numerous patients were lost to follow-up or dropped out of the studies (Brown, et al., 2025; Rodríguez Lorenzo, et al., 2024; Sapci, et al., 2023; Saunders, et al., 2021; Hyldig, et al., 2019; Kirsner, et al., 2019; Singh, et al., 2019; Tanaydin, et al., 2018; Galiano, et al., 2018; Fleming, et al., 2018; Crist, et al., 2017; Lee, et al., 2017; Lo Torto, et al., 2017; Cooper and Bas, 2016; Marston, et al., 2015; Matatov, et al., 2013; Karlakki, et al., 2013; Hudson, et al., 2013; Gabriel, et al., 2013; Fraccalvieri, et al., 2012; Armstrong, et al., 2012; Armstrong, et al., 2011; Lerman, et al., 2010a, Lerman, et al., 2010b).

Brown et al. (2025) published the SUNRISE randomized clinical trial, a phase three individual-participant study. The objective was to evaluate the effectiveness of single use, battery powered iNPWT in reducing the rate of surgical site infection (SSI) in adults undergoing emergency laparotomy with primary skin closure. Adult patients undergoing emergency laparotomy in 22 hospitals in the UK and 12 hospitals in Australia between December 18, 2018, and May 25, 2021, were recruited and followed for 30 days. Participants were randomized 1:1 to receive incisional negative pressure wound therapy (iNPWT) (n = 411), which involved a specialized dressing used to create negative pressure over the closed wound vs the surgeon's choice of wound dressing (n = 410). Randomization and dressing application occurred in the operating room at the end of the surgical procedure. The primary outcome measure was SSI up to 30 days post procedure, evaluated by an assessor masked to the randomized allocation and using criteria from the US Centers for Disease Control and Prevention. There were seven secondary outcomes, including hospital length of stay, postoperative complications up to 30 days, hospital readmission for wound-related complications within 30 days, wound pain, and quality of life, serious adverse events, and mortality. A total of 840 patients were randomized (536 from the UK; 304 from Australia). Overall, 52% were female; the mean age was 63.8 (range, 18.8 to 95.3) years. After post randomization exclusions (N = 52), 394 participants per group were included in the primary analysis. The number of participants who had an SSI in the iNPWT group was 112 of 394 (28.4%), compared with 108 of 394 (27.4%) in the surgeon's preference group (relative risk 1.03; $P = 0.78$). This finding was consistent across the preplanned subgroup analyses, including degree of contamination, presence of a stoma, participant BMI, skin preparation used, and across all preplanned sensitivity analyses. Of the seven secondary outcomes, six showed no significant difference, including hospital readmission, quality of life, and hospital stay (median, eight [6-14] days in the iNPWT group and none [6-14.5] days in the surgeon's preference group [$P = 0.21$]). Routine application of iNPWT to the closed surgical wound after emergency laparotomy did not prevent SSI more than other dressings. The findings did not support the routine use of iNPWT for the reduction of SSI in adults undergoing emergency laparotomy.

In the PICO-Vasc Study, Rodríguez Lorenzo et al. (2024) reported a prospective randomized controlled trial evaluating incisional negative pressure wound therapy (iNPWT) using PICO-7 therapy compared with a standard transparent waterproof dressing for longitudinal inguinal (groin) incisions following elective revascularization procedures for peripheral arterial disease. Individuals were excluded for: age < 18 years, pregnancy, active inguinal infection, cognitive impairment, and declining participation. A total of 133 groin incisions were randomized (66 in the intervention group and 67 in the control group). Wound healing and complications were assessed on postoperative days 5, 14, and 30. The primary outcome was the 30-day surgical site infection rate, defined and classified according to Centers for Disease Control and Prevention criteria; the secondary outcome was the 30-day surgical site occurrence rate (other than surgical site infection), defined as wound dehiscence, seroma or lymphocele, hematoma, and lymphorrhagia. The study reported that iNPWT did not reduce 30-day surgical site infection rates (p=0.53) or 30-day surgical site occurrence rates (p=0.42); however, early (14-day) surgical site occurrence rates (p=0.037)and seroma rates (p=0.008) were reported as significantly reduced in the iNPWT group. Adverse event were ruled out and the study described limitations including an insufficient surveillance timeframe for identifying surgical site infection, inability to double blind due to the nature of iNPWT, potential assessment bias, and single-center design.

Sapci et al. (2023) conducted a single-center randomized controlled trial evaluating the effect of incisional negative pressure wound therapy compared with standard gauze dressings in 298 adults undergoing elective, open, high-risk reoperative colorectal surgery. Patients were randomized in a 1:1 ratio, with the primary outcome being superficial surgical site infection within 30 days. Secondary outcomes included deep and organ-space surgical site infections, postoperative complications, and length of hospital stay. Follow-up assessments occurred at postoperative days 7 and 30, with no loss to follow-up reported. The study found no statistically significant difference in 30-day superficial surgical site infection rates between groups (14.1% control vs. 9.4% incisional negative pressure wound therapy; p = 0.28), and no differences in secondary outcomes. No adverse events related to incisional negative pressure wound therapy were reported. The authors concluded that incisional negative pressure wound therapy did not reduce surgical site infections or overall complications in this high-risk population.

Saunders et al. (2021) conducted a systematic review and meta-analysis to compare the prophylactic use of the PICO single-use negative pressure wound therapy system to conventional dressings in the prevention of surgical-site complications after closed surgical incisions. Twenty-nine studies (n=5614) including 11 randomized controlled trials, 13 observational studies and five conference abstracts met inclusion criteria. The inclusion criteria were studies that enrolled patients with a closed surgical incision and at any risk factor for surgical-site complications. The intervention was the PICO compared to any non-negative pressure wound therapy (NPWT) dressing. Studies that included patients with an open surgical incision or any non-surgical wound, as well as studies that did not use PICO, were excluded. Data was assessed from orthopedic, colorectal, obstetric, breast, vascular, and cardiovascular specialty procedures. Results showed that surgical site infections were reduced by 63% with PICO compared to conventional dressings, and noted a significant decrease for wound dehiscence, seromas, necrosis, and mean hospital length of stay. Surgical site complications of hematomas, delayed healing, abnormal scarring, and time of healing did not show significant difference between the two groups. The author noted limitations of the analysis included: small patient populations, heterogeneity of reported outcomes, variation in the criteria used to define a patient as high risk, and lack of blinding of patients and clinicians for most studies. Other limitations include the fact that the authors did not report the number of patients per study or the follow-up time of the studies, and conference abstracts were included.

In a multicenter, prospective randomized controlled trial, Kirsner et al. (2019) compared the efficacy and safety of a single-use negative pressure wound therapy (s-NPWT) system versus traditional NPWT (t-NPWT) for the management of lower extremity ulcers, including both venous leg ulcers (VLUs), diabetic foot ulcers (DFUs). The intent to treat (ITT) population was composed of 161 patients (101 with VLUs, 60 with DFUs) and 115 patients completed follow-up in the per protocol population (PP) (64 in the s-NPWT group and 51 in the t-NPWT group). The primary objective was to assess an s-NPWT system versus t-NPWT (different brands) for the percentage change in target wound area over a 12-week period from baseline. Secondary endpoints were the percentage change in the target ulcer depth and volume, time (in days) to achieve complete target ulcer closure, and the proportion of patients that achieved confirmed complete target ulcer closure. The study included adult patients with either a VLU present for more than four weeks and measuring 2-36 cm^2 in surface area or a DFU present for more than four weeks and measuring 0.5-10 cm^2 in surface area and a confirmed adequate arterial supply. Exclusion criteria included suspected or known allergies to the components of the different NPWT systems; pregnancy; participation in other research within 30 days of screening; ulcers deemed by the investigator to be highly exuding; anatomic location not amendable to the creation of an airtight seal; malignancy in the target ulcer; concurrent diagnosis of vasculitis or claudication; current administration of systemic chemotherapy or corticosteroids; previous treatment with NPWT or hyperbaric oxygen within seven days of screening, leukopenia, thrombocytopenia, anemia, two-fold or higher increase in bilirubin levels, three times or higher increase in hepatic enzymes. For individuals with nondiabetic ulceration, exclusion criteria also included: ulcers whose etiology was nonvenous (e.g., sickle-cell anemia, pyoderma gangrenosum, vasculitis), the presence of deep vein thrombosis, the refusal or inability to tolerate compression therapy, exposure of muscle, tendon or bone in the target ulcer, the size of the target ulcer was >15 cm in one linear direction. For individuals with DFU, exclusion criteria also included: diagnosis of active Charcot foot syndrome and the location of the target wound on the toes. The ITT populations attended at least one follow-up post baseline visit. Primary endpoint analyses on wound area reduction was statistically significant reduction in favor of s-NPWT (p=0.003) for the PP population and for the ITT population (p<0.001). Changes in wound depth (p=0.018) and volume (p=0.013) were also better with s-NPWT. Faster wound closure was observed with s-NPWT (p=0.019) in the ITT population. Wound closure occurred in 45% of patients in the s-NPWT group; 22.2% of patients in the t-NPWT group (p=0.002). Median estimate of the time to wound closure was 77 days for s-NPWT. No estimate could be provided for t-NPWT due to the low number of patients achieving wound closure. Device-related AEs were more frequent in the t-NPWT group (41 AEs from 29 patients) than in the s-NPWT group (16 AEs from 12 patients). This study is limited by small sample size.

In a multicenter, comparative, randomized controlled trial the mechanically powered SNaP Wound Care System was compared with the electrically powered VAC Therapy System. Initial enrollment included 132 individuals. Seventeen patients dropped from study before treatment started for unknown reasons leaving 115 individuals available for follow-up data (i.e., 59 SNaP; 56 VAC). The inclusion criteria was for patients aged ≥18 years; lower extremity venous ulcer or diabetic ulcer with a surface area <100 cm^2 but larger than 1 cm^2, and <10 cm in widest diameter. Wounds were to have been present for >30 days despite appropriate wound care prior to entry. Adequate blood perfusion defined as either transcutaneous oxygen measurements of the dorsum of the foot >30 mmHg, skin perfusion pressure >30 mmHg, or an ankle/brachial index between 0.7 and 1.2. The wound was required to be in a location amendable to creation of an airtight seal using the provided dressings. Exclusion criteria included: active infection (redness, swelling, pain, purulent exudate), untreated osteomyelitis, pregnancy, allergies to wound care products used in the study, etiologies of the wound that included malignancy, burn, collagen vascular disease, sickle cell, vasculopathy, or pyoderma gangrenosum, a diagnosis of active Charcot foot syndrome, wound location on toes or plantar surface of foot, uncontrolled hyperglycemia (glycated hemoglobin [HbA1C] >12%), end-stage renal disease requiring dialysis, active chemotherapy treatment, previous treatment with a NPWT device, growth factors, hyperbaric oxygen, or bioengineered tissue product within 30 days of enrollment. Patients were not enrolled if they exhibited greater than 30% wound surface area reduction in size at one week after the screening visit.

Each subject was randomly assigned (1:1) to treatment with either system in conjunction with appropriate off-loading and compression therapy. Subjects were evaluated on a weekly basis to complete wound closure (defined as complete epithelialization without drainage) or for up to 16 weeks of therapy. Dressing changes were performed following manufacturer recommended instructions. Wound size and age of the wounds varied between the two groups. The primary outcomes evaluated in this study were percent wound closure at 4, 8, 12, and 16 weeks. To establish noninferiority to traditional NPWT, this study was powered assuming 80% wound closure with an 18.5% standard deviation (derived from previous study wounds treated with the SNaP system) for both groups at 16 weeks using a margin of noninferiority of 12.5%. Primary end point analysis of wound size reduction found that SNaP-treated subjects demonstrated non-inferiority to the VAC treated subjects at 4, 8, 12, and 16 weeks (p=0.0030, 0.0130, 0.0051, and 0.0044, respectively). Eighty-three patients (n=41 SNaP, n=42 VAC) completed the study with either healing or 16 weeks of therapy. Device related adverse events and complications such as infection were similar between treatment groups. The authors reported that wound types that may respond best to each form of wound interface layer during NPWT still need to be defined in additional studies. Additionally, further comparative effectiveness studies specifically designed to assess specific wound etiologies are warranted (Armstrong, et al., 2012).

The interim analysis of the above study compared the mechanically powered SNaP Wound Care System to the traditional electrically powered VAC Therapy System in the treatment of chronic lower extremity wounds. This 12-center randomized controlled trial of patients with noninfected, nonischemic, nonplantar lower extremity wounds enrolled 65 patients. The trial evaluated treatment for up to 16 weeks or until complete closure was achieved. Fifty-three patients (n=27 SNaP, n=26 VAC) completed at least 4 weeks of therapy. Thirty-three patients (n=18 SNaP, n=15 VAC) completed the study with either healing or 16 weeks of therapy. At the time of planned interim analysis, no significant differences in the proportion of subjects healed between the two groups were found. The percent wound size reduction between treatment groups was not significantly different at 4, 8, 12, and 16 weeks, with noninferiority analysis at 4 weeks of treatment reaching p=0.019. Wound size and age of wound differed between the two groups. Initial wound size in the standard VAC group was 8.8 sq cm and 4.3 sq cm in the SNaP group. Age of wound was 14 months in the VAC group and 8.3 months in the SNaP group. The proportion of patients experiencing one or more device-related adverse events was similar between the VAC and SNaP treatment groups (Armstrong, et al., 2011).

In a retrospective study with historical controls Lerman et al. (2010b) compared NPWT using the SNaP device (n=21) with wound care protocols that included the use of use Apligraf, Regranex and skin grafting (n=42) for treatment of lower extremity ulcers. There were a total of 36 subjects enrolled prospectively in the first phase of the study, and 21 subjects completed treatment with the SNaP device. Of the 15 subjects that did not complete the study, seven subjects had complications (e.g., allergic reaction, wound infection) that required premature termination of SNaP treatment. Compared with the matched controls, there was a 47.4 % absolute improvement in the percentage of wounds healed when subjects were treated with the SNaP device as compared with modern dressings over a 4-month period. The study is limited by study design, the multiple modalities used in treatment of the control group, and the large number of dropouts.

In a prospective multicenter study, Hudson et al. (2013) assessed overall functionality and performance of the disposable PICO NPWT system including the ability of the system to manage exudate without a canister, concomitant delivery of NPWT and wound progress towards healing during the treatment phase. The study included 20 individuals. Sixteen had closed surgical wounds, two had traumatic wounds and two received meshed split thickness skin grafts. The mean study duration was 10.7 days (range: 5–14 days) and the mean dressing wear time per individual patient was 4.6 days (range: 2–11). A total of 55% of the wounds had closed by the end of the 14-day study or earlier, with 40% of wounds progressing to closure. Two wounds were clinically infected, and a further wound had clinical signs of infection at recruitment. Two of these wounds were successfully skin grafted during the treatment period. One device-related adverse event observed small blister-like lesions around the wound associated with the removal of adhesive film fixation strips. This study is limited by small sample size and lack of a comparator.

In a retrospective study, Gabriel et al. (2013) evaluated use of the disposable, single-patient-use NPWT system (SP-NPWT) V.A.C.Via Therapy over dermal regeneration template (DRT) and/or skin grafts. SP-NPWT was initiated over a DRT and/or skin graft in 33 patients with 41 graft procedures. Endpoints were recorded and compared to a historical control group of 25 patients with 28 grafts bolstered with traditional rental NPWT (V.A.C.). Mean age was less for the SP-NPWT group versus the control and there were significantly more patients with peripheral vascular disease (PVD) in the SP-NPWT group compared with the control (12 versus 0, respectively). A greater number of acute wounds were present in the SP-NPWT group versus the control (26 versus 10, respectively). All other patient demographics and wound characteristics were similar. Mean follow-up time was 6.4 months for the SP-NPWT group and 12.7 months for the control group. The primary endpoint was time to hospital discharge, duration of SP-NPWT and graft take rate were collected and compared to a historical control group of patients who received traditional rental NPWT over dermal regeneration template (DRT) and/or skin grafts. The average length of inpatient hospital stay was 0 days for the SP-NPWT group and six days for the control group. The average duration of SP-NPWT post-DRT or skin graft was 5.6 days and 7.0 days for the control. This study is limited by small sample size, lack of a comparator, and observer bias in estimating graft take. The authors reported that considerably more controlled research is necessary to measure efficacy of SP-NPWT in the adjunctive management of various wound types.

Singh et al. (2019) performed a meta-analysis of 30 studies evaluating single-use NPWT systems for treating closed wounds. Randomized controlled trials and observational studies were assessed across specialties including vascular surgery, cardiothoracic, lower extremity, obstetrics and colorectal/abdominal. Results demonstrated that the Prevena system performed significantly better at reducing the incidence of surgical site infections in comparison to traditional and advanced wound dressings. The reported limitations include heterogeneity of data and lack of high-quality studies for the review.

Scalise et al. (2016) conducted a systematic review to evaluate incisional negative pressure wound therapy (INPWT)'s effect on surgical sites healing by primary intention. The study included the Prevena and Pico systems which have been the focus of a new investigation on possible prophylactic measures to prevent complications via application immediately after surgery in high-risk, clean, closed surgical incisions. A total of six randomized controlled trials, five prospective cohort studies and seven retrospective analyses were included. The primary outcomes included incidence of complications (infection, dehiscence, seroma, hematoma, skin and fat necrosis, skin and fascial dehiscence or blistering) and other variables influenced by applying INPWT (re-operation and re-hospitalization rates, time to dry wound). The study sample included 1042 incisions on 1003 patients. Most of the studies in this review evaluated the use of INPWT in orthopedics. The remaining studies included INPWT used post cardiac surgery and for abdominal incisions. The authors reported that the studies showed a decrease in the incidence of infection, sero-hematoma formation and on the re-operation rates when using INPWT. A lower level of evidence was found on dehiscence, decreased in some studies, and was inconsistent to make a conclusion. Because of limited studies, it is difficult to justify strong assertion and recommendation regarding the effect of INPWT on the rate of skin necrosis and blistering and of time until attainment of dry wound. The authors concluded that although INPWT is safe and potentially beneficial, data is insufficient to recommend widespread use of this technology.

Professional Societies/Organizations
The American Society of Plastic Surgeons (ASPS) evidence-based clinical practice guideline for chronic wounds of the lower extremity states, "Although the wound care literature is rife with uncontrolled studies reporting the effectiveness of negative pressure wound therapy, few prospective randomized trials exist. Despite a lack of strong evidence to support its use, negative pressure wound therapy has gained wide acceptance by multiple specialties for a myriad of wounds" (ASPS, 2007).

The American College of Foot and Ankle Surgeons (ACFAS) 2006 diabetic foot disorders clinical practice guideline addresses the treatment of diabetic foot infections. The authors state the primary treatment goal for diabetic foot ulcers is to obtain wound closure as expeditiously as possible. The authors state that along with other dressings, NPWT may be useful to aid in the healing of surgical wounds of the diabetic foot. If the wound fails to show signs of healing, the patient's vascularity, nutritional status, infection control, and wound offloading must be re-evaluated (Frykberg, et al., 2006).

An endorsement for a particular NPWT device was not located in any professional society guideline.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Cavalcante-Silva et al. (2024) conducted a review of the available literature that provides direct evidence that chronic wound burden and outcomes are disproportionately worse among African American, Hispanic, and Native American populations, particularly in the context of diabetes mellitus (DM). Among individuals with DM, the incidence of chronic wounds is modestly higher in African American (6.3%), Hispanic (6.4%), and Native American (7.0%) individuals compared with White individuals (6.0%); however, because DM prevalence itself is approximately twofold higher in these populations (14.7–15.3% vs 7.3% in White individuals), the overall population burden of chronic wounds is substantially greater. Downstream outcomes show clearer disparities: African American, Hispanic, and Native American individuals with DM have a 44%, 33%, and 47% higher risk, respectively, of chronic wound–related complications such as non-traumatic lower extremity amputation (NLEA) and prolonged hospitalization compared with White individuals. Regardless of insurance status, NLEA rates are reported as 34.0 per 100,000 population in underrepresented groups versus 17.7 per 100,000 among White individuals, corresponding to a 1.78–2.90-fold higher risk of amputation. Social deprivation is identified as a directly associated factor, with evidence that individuals living in more socially deprived areas have higher risks of chronic wounds and NLEA and are significantly less likely to receive high-quality diabetes care; a U.S. study of 31,934 patients with DM demonstrated poorer diabetes care quality in more deprived areas, and a U.K. population study of 176,359 patients identified social deprivation as an independent risk factor for developing chronic wounds. Nutrition is another area with direct evidence: in a study of 50 patients with chronic wounds, African American, Hispanic, and Native American individuals experienced higher rates of food insecurity than White individuals, a condition associated with poorer diet quality and plausibly impaired wound healing. Together, these data demonstrate clear racial/ethnic and place-based inequities in chronic wound outcomes and complications, with direct links to social deprivation and nutrition-related factors.

References

1. American Society of Plastic Surgeons (ASPS). Evidence based practice guidelines. Chronic wounds of the lower extremity. May 2007 (archived). Accessed Feb 19, 2026. Available at URL address: https://www.plasticsurgery.org/for-medical-professionals/quality-and-registries/evidence-based-clinical-practice-guidelines

2. Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparison of negative pressure wound therapy with an ultraportable mechanically powered device vs. traditional electrically powered device for the treatment of chronic lower extremity ulcers: a multicenter randomized-controlled trial. Wound Repair Regen. 2011 Mar-Apr;19(2):173-80.

3. Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial. Wound Repair Regen. 2012 May-Jun;20(3):332-41.

4. Brown, J., Clouston, H., Coe, P., Duarte, R., Duff, S., Fish, R., ... & Clark, M. (2025). Negative Pressure Dressings to Prevent Surgical Site Infection After Emergency Laparotomy: The SUNRRISE Randomized Clinical Trial. *JAMA*, *333*(10), 853-863.

5. Cavalcante-Silva J, Fantuzzi G, Minshall R, Wu S, Oddo VM, Koh TJ. Racial/ethnic disparities in chronic wounds: Perspectives on linking upstream factors to health outcomes. Wound Repair Regen. 2024 Sep-Oct;32(5):770-779. doi: 10.1111/wrr.13200. Epub 2024 Jun 29. PMID: 38943351; PMCID: PMC11578790.

6. Cooper HJ, Bas MA. Closed-Incision Negative-Pressure Therapy Versus Antimicrobial Dressings After Revision Hip and Knee Surgery: A Comparative Study. J Arthroplasty. 2016 May;31(5):1047-52.

7. Crist BD, Oladeji LO, Khazzam M, Della Rocca GJ, Murtha YM, Stannard JP. Role of acute negative pressure wound therapy over primarily closed surgical incisions in acetabular fracture ORIF: A prospective randomized trial. Injury. 2017 Jul;48(7):1518-1521.

8. Dohmen PM, Markou T, Ingemansson R, et al. Use of incisional negative pressure wound therapy on closed median sternal incisions after cardiothoracic surgery: clinical evidence and consensus recommendations. Med Sci Monit. 2014;20:1814-1825. Published 2014 Oct 4.

9. Fleming CA, Kuteva M, O'Hanlon K, O'Brien G, McGreal G. Routine use of PICO dressings may reduce overall groin wound complication rates following peripheral vascular surgery. J Hosp Infect. 2018 May;99(1):75-80.

10. Fraccalvieri M, Sarno A, Gasperini S, et al. Can single use negative pressure wound therapy be an alternative method to manage keloid scarring? A preliminary report of a clinical and ultrasound/colour-power-doppler study. Int Wound J. 2012 Jun 21.

11. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, et al. Diabetic foot disorders a clinical practice guideline (2006 revision). J Foot Ankle Surg. 2006 Sep-Oct;45(5 Suppl):S1-S66.

12. Gabriel A, Thimmappa B, Rubano C, Storm-Dickerson T. Evaluation of an ultra-lightweight, single-patient-use negative pressure wound therapy system over dermal regeneration template and skin grafts. Int Wound J. 2013 Aug;10(4):418-24.

13. Galiano RD, Hudson D, Shin J, van der Hulst R, Tanaydin V, Djohan R, et al. Incisional Negative Pressure Wound Therapy for Prevention of Wound Healing Complications Following Reduction Mammaplasty. Plast Reconstr Surg Glob Open. 2018 Jan 12;6(1):e1560.

14. Hudson DA, Adams KG, Huyssteen AV, Martin R, Huddleston EM. Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system. Int Wound J. 2013 May 7.

15. Hyldig N, Vinter CA, Kruse M, Mogensen O, Bille C, Sorensen JA, et al. Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women: a pragmatic randomised clinical trial. BJOG. 2019 Apr;126(5):628-635.

16. Karlakki S, Brem M, Giannini S, Khanduja V, Stannard J, Martin R. Negative pressure wound therapy for managementof the surgical incision in orthopaedic surgery: A review of evidence and mechanisms for an emerging indication. Bone Joint Res. 2013 Dec 18;2(12):276-84.

17. Kirsner R, Dove C, Reyzelman A, Vayser D, Jaimes H. A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities. Wound Repair Regen. 2019 Sep;27(5):519-529.

18. Kuplicki S. How to select the appropriate negative pressure wound therapy device for your patient. WoundSource [Internet]. Jun 30, 2016. Accessed Feb 19, 2026. Available at URL address: https://www.woundsource.com/blog/how-select-appropriate-negative-pressure-wound-therapy-device-your-patient

19. Lee AJ, Sheppard CE, Kent WD, Mewhort H, Sikdar KC, Fedak PW. Safety and efficacy of prophylactic negative pressure wound therapy following open saphenous vein harvest in cardiac surgery: a feasibility study. Interact Cardiovasc Thorac Surg. 2017 Mar 1;24(3):324-328.

20. Lerman B, Oldenbrook L, Ryu J, Fong KD, Schubart PJ. The SNaP Wound Care System: a case series using a novel ultraportable negative pressure wound therapy device for the treatment of diabetic lower extremity wounds. J Diabetes Sci Technol. 2010a Jul 1;4(4):825-30.

21. Lerman B, Oldenbrook L, Eichstadt SL, Ryu J, Fong KD, Schubart PJ. Evaluation of chronic wound treatment with the SNaP wound care system versus modern dressing protocols. Plast Reconstr Surg. 2010b Oct;126(4):1253-61.

22. Marston WA, Armstrong DG, Reyzelman AM, Kirsner RS. A Multicenter Randomized Controlled Trial Comparing Treatment of Venous Leg Ulcers Using Mechanically Versus Electrically Powered Negative Pressure Wound Therapy. Adv Wound Care (New Rochelle). 2015 Feb 1;4(2):75-82.

23. Matatov T, Reddy KN, Doucet LD, Zhao CX, Zhang WW. Experience with a new negative pressure incision management system in prevention of groin wound infection in vascular surgery patients. J Vasc Surg. 2013 Mar;57(3):791-5.

24. Rodríguez Lorenzo L, Salto EA, González Cañas E, Madrazo González Z, Espi MS, Giménez Gaibar A. Incisional Negative Pressure Wound Therapy After Revascularisation Surgery in Patients with Peripheral Arterial Disease: A Randomised Trial (PICO-Vasc Study). Eur J Vasc Endovasc Surg. 2024 Aug;68(2):238-244. doi: 10.1016/j.ejvs.2024.04.031. Epub 2024 Apr 25. PMID: 38677468.

25. Sapci I, Camargo M, Duraes L, Jia X, Hull TL, Ashburn J, Valente MA, Holubar SD, Delaney CP, Gorgun E, Steele SR, Liska D. Effect of Incisional Negative Pressure Wound Therapy on Surgical Site Infections in High-Risk Reoperative Colorectal Surgery: A Randomized Controlled Trial. Dis Colon Rectum. 2023 Feb 1;66(2):306-313. doi: 10.1097/DCR.0000000000002415. Epub 2022 Apr 1. PMID: 35358097.

26. Saunders C, Nherera LM, Horner A, Trueman P. Single-use negative-pressure wound therapy versus conventional dressings for closed surgical incisions: systematic literature review and meta-analysis. BJS Open. 2021;5(1):zraa003.

27. Scalise A, Calamita R, Tartaglione C, Pierangeli M, Bolletta E, Gioacchini M, et al. Improving wound healing and preventing surgical site complications of closed surgical incisions: a possible role of Incisional Negative Pressure Wound Therapy. A systematic review of the literature. Int Wound J. 2016 Dec;13(6):1260-1281.

28. Singh DP, Gabriel A, Parvizi J, Gardner MJ, D'Agostino R Jr. Meta-Analysis of Comparative Trials Evaluating a Single-Use Closed-Incision Negative-Pressure Therapy System. Plast Reconstr Surg. 2019 Jan;143(1S Management of Surgica Incisions Utilizing Closed-Incision Negative-Pressure Therapy):41S-46S.

29. Stannard JP, Volgas DA, McGwin G 3rd, Stewart RL, Obremskey W, Moore T, Anglen JO. Incisional negative pressure wound therapy after high-risk lower extremity fractures. J Orthop Trauma. 2012 Jan;26(1):37-42.

30. Stefanos B, Aliano K, Phillips LG and Norbury WB. Sabiston Textbook of Surgery. 2022. Wound Healing. Chapter 6, 119-149.

31. Tanaydin V, Beugels J, Andriessen A, Sawor JH, van der Hulst RRWJ. Randomized Controlled Study Comparing Disposable Negative-Pressure Wound Therapy with Standard Care in Bilateral Breast Reduction Mammoplasty Evaluating Surgical Site Complications and Scar Quality. Aesthetic Plast Surg. 2018 Feb 13.

32. U.S. Food and Drug Administration (FDA). FDA Safety Communication. Negative Pressure Wound Therapy Systems-Preliminary Public Health Notification. Updated Aug 30, 2013 (archived). Accessed Feb 19, 2026. Available at URL address: https://wayback.archive-it.org/7993/20170112165249/http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm190704.htm

33. U.S. Food and Drug Administration (FDA). 510(k) premarket notification database. Product code(s): OMP, OKO. Page Last Updated: Feb 16, 2026. Accessed Feb 19, 2026. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Revision Details

Type of Revision	Summary of Changes	Date

Annual Review	• Removed policy statement for powered negative pressure wound therapy • Revised policy statement for non-powered mechanical wound care devices and single use battery-powered devices	5/15/2026
Annual Review	• Revised policy statements for powered negative pressure wound therapy (NPWT)/vacuum-assisted closure (VAC) for nonhealing wounds. • Removed policy statements for powered NPWT	5/15/2025
Annual Review	• No changes to coverage.	5/15/2024