MEDICAL POLICY

Excellus
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Medical Policy Title	**Negative Pressure Wound Therapy (Vacuum-Assisted Closure)**
Policy Number	**1.01.38**
Current Effective Date	**September 17, 2026**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

The focus of this policy is for the use of negative pressure wound therapy (NPWT) in the outpatient setting.

POLICY STATEMENT(S)

I. Negative pressure wound therapy (NPWT) using a powered NPWT device is considered **medically appropriate** when **ALL** of the following are met:

A. In the absence of the following contraindications in accordance with the U.S. Food and Drug Administration (FDA):

1. Necrotic tissue with eschar present;
2. Untreated osteomyelitis;
3. Non-enteric and unexplored fistulas;
4. Malignancy in the wound;
5. Exposed vasculature, nerves, anastomotic site, or organs;

B. For **ANY** of the following indications:

1. Skin ulcers refractory to a complete wound therapy program including **any** of the following:

a. chronic stage III or IV pressure ulcers (refer to the Description section for definitions of stages);

b. neuropathic (e.g., diabetic) ulcers;

c. venous or arterial insufficiency ulcers; **or**

d. chronic ulcers (those present for at least 30 days) of mixed etiology; (When there are recurrent requests for treatment of the same ulcer site, patient adherence with measures for pressure relief and skin care will be taken into consideration.);

2. Complications of surgically created wounds (e.g., infection, dehiscence), which may include the use of skin grafts to assist in wound closure; **or**

3. Traumatic wounds (e.g., preoperative flap or graft, exposed bones and tendons), wounds refractory to standard wound regimens, or burns, where there is documentation of the medical necessity for improved formation of granulation tissue that cannot be achieved by other available topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments).

II. NPWT following pilonidal cyst/sinus excision is considered **investigational**.

III. NPWT using a non-powered NPWT system (e.g., the SNaP system, Prevena system) or a battery-operated, disposable system (e.g., the PICO system) is considered **investigational** in the treatment of acute or chronic wounds.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Medical documentation of **ALL** the following is required for consideration of NPWT:

A. A physician must issue a prescription or written order for the device;

B. Documentation of the history, wound type, previous treatment regimens (where applicable), and current wound management for which the device is being ordered must be submitted. The documentation, which should be reflected in the medical record, must include an assessment of wound healing progress; the length of sessions in use; dressing types and frequency of change; changes in the wound condition, including the precise wound length, width, and depth measurements; presence of granulation and necrotic tissue; and concurrent measures being addressed relative to wound therapy (e.g., debridement, nutritional concerns, use of support surfaces, positioning, incontinence control) and any co-morbid conditions (e.g., diabetes);

C. Weekly wound measurements are performed to document progress in wound healing. A steady decrease in wound volume must be noted from week to week.

II. The average length of treatment is four (4) to six (6) weeks. For patients who are not surgical candidates, NPWT may be continued as long as satisfactory progress is documented;

III. The goal, or endpoint, of wound therapy is satisfactory healing. Satisfactory healing is defined as obliteration of the wound cavity sufficient to allow surface dressings; closure of the wound by suture, myocutaneous flap, or skin graft (delayed primary intention); or complete healing of the wound (delayed secondary closure).

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

DESCRIPTION

NPWT, or vacuum-assisted wound therapy, is the controlled application of sub-atmospheric pressure to a wound. Powered NPWT systems include a vacuum pump, drainage tubing, and a dressing set. The pump may be stationary or portable, relies on AC or battery power, allows for regulation of the suction strength, has alarms to indicate loss of suction, and has a replaceable collection canister. The dressing sets contain either foam or gauze dressing that is placed in the wound and an adhesive film drape for sealing the wound. The drainage tubes come in a variety of configurations, depending on the dressings used or wound being treated.

The electric pump applies intermittent or continuous negative pressure to an open-cell foam or gauze wound dressing. The dressing evenly distributes pressure to the wound surface. In early stages of healing, fluid is withdrawn by the device, reportedly removing inhibitory factors and reducing bacterial counts. In later stages, tensile forces applied to surrounding tissues by the dressing are thought to stimulate cellular proliferation and protein synthesis.

NPWT has been used for chronic, non-healing diabetic skin ulcers, venous/vasculitis ulcers, decubitus ulcers, burns, degloving injuries, acute wounds, post-sternotomy mediastinitis, and dehisced or open surgical wounds.

A pressure ulcer is a localized injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure or pressure in combination with shear and/or friction. Pressure ulcers are defined by stages:

I. Stage I: Intact skin with non-blanchable redness of a localized area, usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

II. Stage II: Partial-thickness loss of dermis presenting as a shallow open ulcer with a red, pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

III. Stage III: Full-thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, and muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

IV. Stage IV: Full-thickness tissue loss, with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.

A non-powered, portable, disposable NPWT system, the Smart Negative Pressure (SNaP) Wound Care System, is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds, as well as diabetic and pressure ulcers. The device consists of a cartridge that acts as the negative pressure source, a dressing, and a strap; it can be worn under clothing. The cartridge, which utilizes specialized springs that generate continuous negative pressure and is preset at negative 75, 100, or 125 mmHg, weighs less than three ounces and has a 60 cc capacity. The dressing is a hydrocolloid dressing with an antimicrobial, gauze, wound interface layer. (Powered NPWT systems usually have a foam-based interface layer.)

A single-use, disposable NPWT device, the PICO system, is designed to remove low-to-moderate amounts of exudate. The system uses batteries instead of electrical power, and, instead of using a canister, the exudate is absorbed into the dressing. The pump is programmed to stop working after 168 hours (seven days) of use and will not restart after that time, even with new batteries.

Contraindications to the use of negative pressure wound therapy (NPWT) systems include the following conditions as noted in a 2009 FDA alert: necrotic tissue with eschar, untreated osteomyelitis, nonenteric and unexplored fistulae, malignancy in the wound, exposed nerve, exposed anastomotic site, and exposed organ.

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

SUPPORTIVE LITERATURE

The available studies published in peer-reviewed literature have demonstrated that the use of NPWT has resulted in improvement in wound size sufficient to allow for secondary closure with skin grafting in patients with chronic ulcers, surgically created wounds, and traumatic wounds.

A Cochrane review (Norman 2020) assessed the impact of using NPWT for preventing surgical site infection (SSI), and the cost-effectiveness of NPWT in treating wounds healing through primary closure. A total of 44 randomized, controlled trials (with a total of 7,447 participants) and five economic studies were included. The authors determined that people who undergo primary wound closure of their surgical wound and are treated prophylactically with NPWT following surgery probably experience fewer SSIs than people treated with standard dressings (moderate-certainty evidence). They also raise the possibility that superficial SSI is reduced with little difference in deep SSI. No clear difference in number of deaths or wound dehiscence were found between people treated with NPWT and standard dressings (low-certainty evidence). There were also no clear differences in secondary outcomes where all evidence was low or very low certainty.

A 2022 Cochrane review update (Norman) evaluated NPWT compared with standard dressings for surgical wound healing by primary closure. NPWT was associated with a reduced risk of surgical site infection (SSI) (44 studies [N=11,403]; RR, 0.73; 95% CI, 0.63 to 0.85; I^2=29%). Mortality was lower with NPWT, but this was nonsignificant (11 studies [N=6384]; RR, 0.78; 95% CI, 0.47 to 1.30). No significant difference was found for wound dehiscence, reoperations, or wound-related readmission. The analysis is limited by inclusion of studies with mixed or unclear intervention types, no subgroup analysis for traditional or portable, single-use systems, and no discussion of use specific to outpatients. Uncertainty remains regarding if NPWT compared with a standard dressing reduced or increased the incidence of important outcomes such as mortality, dehiscence, seroma, or if it increased costs. These researchers stated that given the cost and widespread use of NPWT for SSI

prophylaxis, there is an urgent need for larger, well-designed, and well-conducted trials to examine the effects of newer NPWT products designed for use on clean, closed surgical incisions.

The Wound Healing in Surgical Trauma (WHIST) trial (Costa 2020), compared incisional negative pressure wound therapy (iNPWT) to standard wound dressing, to determine efficacy in reducing the rate of deep SSI in wounds associated with surgery for a fracture in the context of major trauma to the lower limb. This randomized, controlled trial (RCT) was conducted at 24 trauma hospitals in the U.K. and included 1,548 patients aged 16 years or older. Results showed no statistically significant difference in the rate of deep SSI at 30 days between iNPWT (5.8%) and standard wound dressing (6.7%). No significant differences were found for any of the secondary outcomes, including quality of life, disability, and local wound-healing complications.

A few studies have explored the use of NPWT after excision in pilonidal disease and have found no benefit of NPWT compared to standard dressings (Martins MAB 2026, Morais LPF 2025). Literature generally concludes that randomized, controlled studies are needed, before conclusions can be drawn regarding the efficacy of NPWT in pilonidal disease. Ensor et al (2024) conducted a RCT to assess whether NPWT could reduce the incidence of surgical wound dehiscence (SWD) compared to conventional passive (CP) dressings following off-midline primary closure for pilonidal sinus disease (PSD). Secondary outcomes included patient quality of life and time to return to normal activities. A total of 50 patients from four (4) tertiary hospitals were randomized equally into NPWT and CP groups. The overall SWD rate was 42% (21/50), with 48% (12/25) in the NPWT group and 36% (9/25) in the CP group ($p = 0.6$). Both groups experienced five deep SWDs (≥5 mm) ($p > 0.9$). Notably, in the NPWT group, SWD was significantly associated with larger excision dimensions ($p = 0.03$). Among wounds that did not dehisce, the median time to healing was similar: 21 days in both groups ($p = 0.7$). There were no statistically significant differences in:

- Return to school/work: NPWT 26.1 ±18.2 days vs. CP 29.3 ±14.7 days ($p = 0.6$)
- Ability to sit normally: NPWT 22.3 ±16.2 days vs. CP 20.1 ±9.4 days ($p = 0.7$)
- Return to physical activity: NPWT 21.6 ±17.2 days vs. CP 40.3 ±2.4 days ($p = 0.2$)

The authors concluded that NPWT did not significantly reduce SWD rates or improve other postoperative outcomes such as pain management, healing time, patient satisfaction, or functional recovery. Limitations of the study included a small sample size, lack of blinding, and potential for attrition and performance bias. Based on these findings, the authors do not recommend NPWT as a routine prophylactic measure following PSD excision with off-midline closure.

Published studies are insufficient to draw conclusions regarding the impact on net health outcomes of the non-powered wound care system (SNaP device) itself, and, in comparison with current care standards. Well-designed comparative studies are needed to answer questions that remain regarding its efficacy and tolerability.

Armstrong et al (2011) conducted an interim analysis of a RCT comparing the SNaP Wound Care System to V.A.C. Therapy for chronic lower-extremity wounds. Final results from this industry-sponsored, multicenter noninferiority trial were published in 2012 (Armstrong). The study enrolled 132 patients with venous or diabetic ulcers (1–100 cm^2, <10 cm diameter) present for over 30 days despite appropriate care. Diabetic ulcers accounted for approximately 30% of cases; no subgroup analyses were performed.

Dressings were changed per manufacturer guidelines: twice weekly for SNaP and three times weekly for V.A.C. Patients were followed for up to 16 weeks or until complete wound closure; 63% completed the study. Intention-to-treat analysis using last observation carried forward demonstrated noninferiority in wound size reduction at 4, 8, 12, and 16 weeks. After adjusting for baseline wound size, SNaP remained noninferior at 4, 12, and 16 weeks. Kaplan-Meier analysis showed no significant difference in complete wound closure rates: 65.6% for V.A.C. and 63.6% for SNaP. Survey data indicated that SNaP required less time for dressing changes and interfered less with mobility and daily activities.

Published studies addressing NPWT systems, including disposable systems (e.g., the PICO system, the Prevena Incision Management system), for the treatment of closed wounds have generally involved small patient populations or risk of bias. Further well-designed, comparative studies are needed before conclusions can be reached regarding the efficacy of disposable systems, the effects of the technology on health outcomes, and the patient population that would benefit from use of these devices.

Karlakki et al (2016) conducted an RCT with 220 patients to assess the PICO device after hip and knee arthroplasties. The device was used for 7 days, including post-discharge. The trial featured a powered intention-to-treat analysis, though evaluators were unblinded. Results showed trends toward reduced hospital stay (0.9 days; 95% CI: -0.2 to 2.5; p=0.07) and fewer wound complications (2.0% PICO vs. 8.4% control; p=0.06), though outliers in the control group influenced length of stay. PICO significantly reduced wound exudate (p=0.007), with grade 4 exudate in 4% of PICO patients vs. 16% in controls. 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) conducted a single-site, parallel-group RCT to evaluate the efficacy of the PICO system for iNPWT following cesarean delivery in women with class III obesity (BMI ≥40), compared to standard surgical dressings. The study initially aimed to enroll 242 participants, but an unplanned interim analysis was performed due to slow recruitment and the publication of larger trials showing no benefit for NPWT. Of 411 eligible patients, 212 were enrolled, with 110 ultimately randomized (55 per group). The interim analysis revealed no statistically significant difference in the primary composite outcome of wound complications (risk difference: 9.1%; 95% CI: -8.3% to 25.8%; p=0.38). The trial was subsequently terminated early. The authors concluded that prophylactic NPWT using the PICO device did not reduce wound complications compared to standard dressings in this patient population.

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 gauze dressing (n=124). The primary composite outcome of groin wound complications, surgical site infections (SSIs), 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). The significant adverse event rates were not different between the two groups (ciNPT vs control: 13% vs 16%; p=.53). The mean length of the initial hospitalization was the same for the ciNPT and control groups (5.2 versus 5.7 days; p=.63). The overall health-related quality of life was similar at baseline and at 14 and 30 days postoperatively for the two groups. The authors concluded that they found no

differences in the 30-day groin wound complications for patients treated with Prevena vs standard gauze dressings.

The SUNPRISE trial was an assessor-masked, pragmatic, phase 3, individual-participant, RCT (SUNPRISE Trial Study Group; Atherton 2025). 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. Patients were followed up for 30 days post procedure to evaluate the effectiveness of iNPWT in reducing the rate of SSI in adults undergoing emergency laparotomy with primary skin closure. Participants were randomized 1:1 to receive 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. 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 [95% CI, 0.83-1.28]; p=.78). The authors concluded that routine application of iNPWT to the closed surgical wound after emergency laparotomy did not prevent SSI more than other dressings.

PROFESSIONAL GUIDELINE(S)

The Wound Healing Society (WHS) diabetic foot ulcer treatment guidelines (Lavery 2024) recommend the following:

- “There should be an ongoing and consistent documentation of wound history, recurrence, and characteristics (location, size, base, exudates, condition of the surrounding skin, staging, and pain) to evaluate wound bed preparation. The rate of wound healing should be evaluated to determine whether treatment is optimal. (Level III). Ongoing evaluation of wound is necessary to evaluate changes in wound characteristics, monitor infection, and evaluate the effectiveness of therapies. Risk factors for poor healing include the duration, size, and depth of the wound.”
- “Patients who fail to show a reduction in ulcer size by 50% or more after 4 weeks of therapy should be reevaluated and other treatments, disease processes, and adherence should be considered. (Level II). Percent change in wound area of DFUs over 4 weeks of treatment is a good predictor of effectiveness of therapy and likelihood of healing.”
- “NPWT (Negative Pressure Wound Therapy) in patients with complex diabetic foot wounds has been shown to increase the proportion of wounds that heal, the time to heal, and reduce the incidence of amputations compared with standard wound care in diabetic lower extremity wounds. NPWT has not been shown to reduce the incidence of infection. (Level I – unchanged). NPWT may improve wound healing by reducing edema, removing bacterial products, and acerating granulation tissue, and should be considered for large or deeper defects. The addition of continuous or intermittent irrigation with saline or antiseptics was hypothesized to reduce infection and accelerate healing.”
- “NPWT with irrigation or instillation has not been shown to improve wound healing or clinical infection in complex DFUs (Level I). The existing literature does not provide clear evidence of NPWT with irrigation improving wound healing or decreasing the risk of infection in diabetic foot ulcers.”

WHS guidelines for the treatment of pressure ulcers (Gould 2024) recommends the following:

- "Incisional negative pressure wound therapy (iNPWT) may reduce post-operative complications after flap reconstruction for pressure ulcers. (Level III - new). There is a growing body of evidence supporting the use of iNPWT in patients at high risk for surgical complications, specifically surgical site infection and wound dehiscence. Wound dehiscence is the most common complication after flap reconstruction for pressure ulcers. The majority of patients with pressure ulcers fit criteria to be considered at high risk for both wound dehiscence and surgical site infection after flap reconstruction."
- "Negative pressure wound therapy (NPWT) is a safe and effective treatment for chronic stage III or IV pressure ulcers. (Level I – no change). NPWT uses negative pressure applied to the wound to remove exudate and debris. Current literature has demonstrated NPWT promotes granulation tissue formation and removal of necrotic tissue, which may lead to the reduction of the size of the wound and shorter the healing times."
- "Use of conventional therapy and negative pressure wound therapy with instillation and dwell (NPWTi-d) may be more beneficial than conventional therapy and negative pressure wound therapy (NPWT) alone in the management of chronic Stage III–Stage IV pressure ulcers. (Level III – new). The literature supports that NPWTi-d, when compared to conventional NPWT alone, may aid in the removal of fibrinous debris and promotion of granulation tissue formation through irrigation of the wound in a negative pressure environment. The most effective type of instillation has not been determined and further research is warranted to examine the benefit of NPWTi-d with regards to wound location, depth, and underlying comorbidities."

WHS guidelines for arterial ulcers (Federman 2024) recommend the following:

- "Topical negative pressure wound therapy (NPWT) may be promising for mixed ulcers. It may have a role as an adjuvant agent in arterial ulcers, but further study is still required, with no new studies noted. A prospective, single-centre study of 50 patients with ischaemic diabetic foot ulcers was randomised to either percutaneous endovascular angioplasty combined with negative pressure closed drainage or percutaneous endovascular angioplasty combined with depuration (Dong B 2022). The findings showed that the ulcer healing rate at 180 days post-surgery was significantly greater in the negative pressure group (52% vs. 12%) ($p = 0.002$, <0.05). (Level II—increased) Topical negative pressure wound therapy has become very popular for many reasons, including the obvious benefit of minimising dressing changes and drainage control. With respect to arterial ulcers, there are at least theoretical reasons to consider effects on blood flow (positive or negative), but updated evidence suggests benefits on healing in the setting of PAD.

WHS guidelines for venous ulcers (Marston 2016) recommend the following:

- "Negative pressure wound therapy may be useful prior to a skin graft/flap by helping promote the development of granulation tissue in the wound base, or postoperatively by preventing shearing and removing exudates. However, its reported experience in venous ulcers is limited (Level II). Negative pressure wound therapy applies negative pressure to help remove fluid, assist in granulation tissue formation, decrease wound size, and help promote skin graft take."

The American Academy of Orthopaedic Surgeons (AAOS) 2022 guidelines for prevention of surgical site infections after major extremity trauma included recommendations for NPWT. The

recommendations from AAOS do not support the continued use of NPWT in patients undergoing fracture fixation due to similar outcomes to standard wound care but with an increased healthcare burden. In patients with high-risk surgical incisions, the AAOS recommends that limited evidence suggests NPWT may be an option; however, its use will be influenced by cost. Importantly, these guidelines do not specifically address use in the outpatient setting.

In 2014, the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of venous and pressure ulcers (Bolton 2014). NPWT was included as a potential second-line intervention if first-line treatments did not result in wound healing (level B evidence). The guidelines indicated that patients must be selected carefully for this procedure per the FDA notice.

National Institute for Health and Care Excellence (NICE) issued guidance on NPWT for diabetic foot problems (2019). They state to, “consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service.”

NICE issued guidance on the prevention and management of pressure ulcers (2014). 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. They also state there is evidence to suggest some benefit in the use of NPWT in other wound areas (for example, surgical wounds).

NICE issued guidance for using NPWT for the open abdomen, 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” (2013). The aims of negative pressure wound therapy (NPWT) for the open abdomen include removing infected material and helping nursing care by reducing escape of fluid; its use may also influence the possibility of delayed primary closure. NPWT for the open abdomen may be used to manage open abdominal wounds (laparostomy) in which the gut and other intraperitoneal organs are exposed. These patients can be divided into three (3) groups: (a) patients who have had surgery that did not involve the gastrointestinal tract, and in whom delayed primary closure is planned within about 1 week (for example, after 'damage-control' surgery for trauma or repair of a ruptured abdominal aneurysm) (b) patients who have had gastrointestinal tract surgery for the management of abdominal sepsis associated with severe gastrointestinal disease (including anastomotic dehiscence, visceral perforation or inflammatory bowel disease) or severe pancreatitis (c) patients who have had abdominal wound dehiscence.

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. 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. The committee considered that there was less certainty about how PICO dressings affect other surgical site complications (such as wound dehiscence, hematoma, delayed healing, or excessive scarring) because of the small number of studies in the analyses.

A 2025 NICE guidance on cesarean birth recommends considering the use of NPWT for women with

a body mass index ≥35 kg/m2 to reduce the risk of wound infections. Routine use of NPWT following cesarean delivery is not recommended.

The Society for Vascular Surgery (SVS), in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine, issued clinical practice guidelines for the management of diabetic foot conditions (Hingorani 2016). They suggested the use of negative pressure wound therapy for chronic diabetic foot wounds that do not demonstrate expected healing progression with standard or advanced wound dressings after four (4) to eight (8) weeks of therapy (Evidence Grade 2B).

The American College of Cardiology (ACC) and American Heart Association (AHA) joint committee clinical practice guidelines for the management of lower extremity peripheral artery disease (Gornik HL 2024) state NPWT can be used to achieve wound healing after revascularization and minor (i.e., digit or partial foot) amputation when primary or delayed secondary closure is not feasible. NPWT is the only wound-healing adjunct supported even by limited data in this population of diabetic ulcers and chronic limb-threatening ischemia (CLTI).

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates NPWT as medical devices. All NPWT including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Aug 17]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Aug 17]

Negative pressure therapy or suction devices cleared by the 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), For you NPWT NP32 Device (For you 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 (CardinalHealth), and the PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew). The Prevena Incision Management System (KCI) is designed specifically for closed surgical incisions.

A nonpowered NPWT device, the SNaP Wound Care System (now SNAP Therapy System) (3M/previously Spiracur, acquired by Acelity in 2015), was cleared for marketing by the FDA in 2009 through the 510(k) pathway (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers.

FDA product code: OMP.

CODE(S)

- Codes may not be covered under all circumstances.

- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
97605	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97606	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
97607 (E/I)	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608 (E/I)	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

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HCPCS Codes

Code	Description
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
A9272 (E/I)	Wound suction, disposable, includes dressing, all accessories and components, any type, each
E2402	Negative pressure wound therapy electrical pump, stationary or portable
K0743	Suction pump, home model, portable, for use on wounds
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq in or less

Code	Description
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 sq in but less than or equal to 48 sq in
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq in

ICD10 Codes

Code	Description
Multiple Codes	

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SEARCH TERMS

Topical negative pressure therapy and Vacuum Assisted Closure therapy

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Negative Pressure Wound Therapy Pumps (LCD L33821) [accessed 2026 Aug 11]

Negative Pressure Wound Therapy Pumps (Policy Article A52511) [accessed 2026 Aug 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid

guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
09/19/02, 07/17/03, 06/17/04, 06/16/05, 05/18/06, 06/21/07, 04/17/08, 05/28/09, 05/27/10, 08/18/11, 10/18/12, 10/17/13, 10/16/14, 10/15/15, 10/20/16, 10/19/17, 11/15/18, 11/21/19, 09/17/20, 09/16/21, 09/15/22, 09/21/23, 09/19/24, 09/18/25, 09/17/26	
Date	**Summary of Changes**
09/17/26	• Annual review, policy intent unchanged.
09/18/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
09/19/02	• Original effective date