

Clinical UM Guideline

Subject: Vacuum Assisted Wound Therapy in the Outpatient Setting

Guideline #: CG-DME-48 Publish Date: 09/27/2023
Status: Reviewed Last Review Date: 08/10/2023

Description

This document addresses the use of vacuum assisted wound therapy (also known as negative pressure wound therapy or NPWT) in the outpatient setting for a variety of wounds, including ulcers related to pressure sores, venous or arterial insufficiency or neuropathy. These devices have several attributes that are used to differentiate them from each other, including being stationary vs. portable, if they are operated electrically vs. mechanically, and if they are reusable or disposable. Each device has some combination of these attributes.

Note: For additional information regarding wound care, please refer to:

- CG-MED-71 Chronic Wound Care in the Home or Outpatient Setting
- SURG.00011 Allogeneic, Xenographic, Synthetic, Bioengineered, and Composite Products for Wound Healing and Soft Tissue Grafting

Clinical Indications

Medically Necessary:

Vacuum assisted wound therapy is considered medically necessary when the individual meets all of the criteria (A, B, and C) below:

- A. A complete wound care program, which meets ALL of the requirements below, has been tried:
 - Documentation in the individual's medical record of evaluation, care, and wound measurements by a licensed medical professional; and
 - 2. Application of dressings to maintain a moist environment; and
 - 3. Debridement of necrotic tissue if present; and
 - 4. Evaluation of and provision for adequate nutritional status; and
 - 5. Underlying medical conditions (e.g., diabetes, venous insufficiency) are being appropriately managed and
- B. An eligible condition is documented (individual must meet one or more of the following):
 - Stage III or IV pressure ulcers (see key terms below) at initiation of vacuum assisted wound therapy, in individuals who
 meet ALL of the following:
 - a. The individual has been appropriately turned and positioned; and
 - b. The individual has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (no special support surface is required for ulcers not located on the trunk or pelvis); and
 - c. The individual's moisture and incontinence have been appropriately managed; or
 - 2. Neuropathic ulcers in individuals who meet BOTH of the following:
 - a. The individual has been on a comprehensive diabetic management program; and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities;or
 - 3. Ulcers related to venous or arterial insufficiency, in individuals who meet ALL of the following:
 - a. Compression bandages and/or garments have been consistently applied; and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities <code>and</code>
 - c. For initiation of therapy in the home setting, presence of the ulcer for at least 30 days $\pmb{\mathsf{pr}}$
 - 4. Dehisced wounds or wound with exposed hardware or bone; $\! \pmb{or} \!$
 - 5. Post sternotomy wound infection or mediastinitis; or
 - Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment; and
- C. The wound to be treated is free from all of the following absolute contraindications to vacuum assisted wound therapy:
 - 1. Exposed anastomotic site; or
 - 2. Exposed nerves; or
 - 3. Exposed organs; or
 - 4. Exposed vasculature; or
 - 5. Malignancy in the wound; or
 - 6. Necrotic tissue with eschar present; **or**
 - 7. Non-enteric and unexplored fistulas; or
 - 8. Untreated osteomyelitis.

Continued use of vacuum assisted wound therapy is considered medically necessary when:

- A. Weekly assessment of the wound's dimensions and characteristics by a licensed health care professional is documented; and
- B. Progressive wound healing is demonstrated.

Not Medically Necessary:

Continued use of vacuum assisted wound therapy is considered **not medically necessary** when the continuation of treatment criteria above have not been met.

Vacuum assisted wound therapy is considered **not medically necessary** for all other applications not meeting the medical necessity criteria above, including for routine prophylactic use in the postoperative setting.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider

reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

97607

97605 Negative pressure wound therapy (eg, 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

entimeters

97606 Negative pressure wound therapy (eg, 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 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 instruction(s) 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 instruction(s) for ongoing care, per session; total

wound(s) surface area greater than 50 square centimeters

HCPCS

A6550 Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and

accessories

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

E2402 Negative pressure wound therapy electrical pump, stationary or portable

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met.

Discussion/General Information

The management and treatment of chronic wounds, including pressure ulcers, remains a challenge. Most chronic wounds will heal only if the underlying cause, such as venous stasis, pressure, or infection, is addressed. In addition, cleaning the wound to remove non-viable tissue, microorganisms and foreign bodies is essential to create optimal conditions for either re-epithelialization or preparation for wound closure with skin grafts or flaps. Debridement, irrigation, whirlpool treatments and wet to dry dressings are common components of chronic wound care.

Vacuum assisted wound therapy is an adjunct to the basic principles of wound care described above. This technique involves applying initial continuous and subsequent intermittent topical negative pressure to an entire wound. The action removes excess fluid from the interstitial space of the wound, thereby enhancing vascular perfusion through vessels compressed by the excess fluid pressure. Additionally, it is believed that removal of excess fluid removes an accumulation of healing-inhibitory factors. Finally, mechanical stretching results in deformation of cellular bridges, which increases cellular proliferation, protein synthesis, and granulation tissue. The net result is accelerated wound closure by re-epithelialization or preparation for wound closure with suturing, skin grafts or flaps (delayed primary intention).

Currently available vacuum assisted wound therapy devices all have some combination of attributes which are used to differentiate them from each other. These attributes include being stationary vs. portable, being operated electrically vs. mechanically, and being reusable or disposable. Stationary devices are usually large and plug into an electrical socket for power. They are intended to be used either in the hospital or some other location where the individual being treated is not very mobile. Newly available portable devices weigh less and are intended for treatment of clinically stable individuals who are mobile. Some devices may operate electrically and others via a mechanical mechanism (for example, being spring loaded) to create the necessary vacuum for treatment. The vast majority of devices available currently are electrically operated. Finally, there are reusable vs. disposable devices. Available stationary devices are all reusable and used in conjunction with disposable items like bandages and tubing. Disposable devices are usually entirely disposable, and no portion of the devices is reused or saved.

NPWT is generally accepted for use in the outpatient setting for the select treatment of wounds, including pressure ulcers, neuropathic ulcers, ulcers related to venous or arterial insufficiency, dehisced wounds, post-sternotomy wounds, and surgically created wounds requiring accelerated granulation therapy, when a complete wound care program has been attempted, and no absolute contraindications to vacuum assisted wound therapy exist. Available evidence supporting the use of traditional electric NPWT systems includes multiple reasonably designed and conducted trials demonstrating a benefit with regard to decreased infection. complication rates, or some parameter of wound healing when compared to standard care (Armstrong, 2005; Blume, 2008; Canaino, 2005; Costa, 2018; De Franzo, 2001; Doss, 2002; Eginton, 2003; Gupta, 2017; Seidel, 2020; Smid, 2017; Stannard, 2009; Stannard 2012). Additionally, a number of case series have reported supportive data (Baillot, 2010; Ford, 2002; Garner, 2001; Hersh, 2001; Moisidis, 2004; Moues, 2004; O'Connor, 2005). When clinically appropriate, vacuum assisted wound therapy may also be applied using battery powered portable devices. A number of studies evaluating battery powered NPWT have demonstrated a benefit with regard to decreased infection and complication rates when compared to standard of care for skin grafts, surgical wounds, traumatic wounds, and diabetic leg ulcers (Carrano, 2021; Gabriel, 2013; Hudson, 2013; Kirsner, 2019 and 2021; León Arellano, 2021; Pellino, 2013 and 2014; Peterson, 2021 Selvaggi, 2014). The use of NPWT in pediatric populations has also been addressed in multiple studies (Baharestani, 2007; Caniano, 2005; Chen, 2017; Gabriel, 2009; Li, 2013; Mouës, 2007; Petkar, 2011; Visser, 2017; Yang 2017). Evidence also shows that the use of NPWT in pediatric populations results in an improvement in wound healing, and that age appears to have no impact on treatment outcomes.

Mechanically powered vacuum assisted wound therapy devices, also referred to as ultraportable vacuum therapy systems, utilize specialized springs to create the vacuum needed for negative pressure wound therapy. Available data addressing this type of mechanically powered vacuum assisted wound therapy include several studies showing improved healing of neuropathic or venous stasis ulcers (Fong, 2010; Lerman, 2010). Other trials have demonstrated non-inferiority to standard NPWT devices for the treatment of lower extremity diabetic or venous stasis ulcers (Armstrong, 2011; Armstrong, 2012; Bradbury, 2015; Marston, 2015). Cuomo and others (2017) evaluated the use of NANOVA[™] Therapy System (KCI USA, Inc. San Antonio, TX) for the treatment of 10 individuals with chronic venous leg ulcers undergoing skin grafting. The device was well tolerated and contributed to successful engraftment after

14 days for 8 individuals, with 2 individuals requiring additional time for healing. Cuomo and colleagues (2021) performed a three part comparative analysis for ultraportable negative pressure wound therapy devices. The first phase evaluated the specifications of each device included in the study; the second phase enrolled 125 individuals with venous leg ulcers, traumatic wounds, diabetic ulcers, surgical wound diastases, and arteriopatic ulcers. The third phase was a systematic review on classic and portable negative pressure wound devices. This study evaluated the advantages and disadvantages of each device and did not compare wound-healing statistics since the wounds were not homogenous. The conclusion of this study is that each wound is unique and a variety of devices allows the wound care treatment team options for the optimal match for successful healing.

Traumatic Wounds

Additional outpatient uses for NPWT have been evaluated for a variety of wounds such as traumatic wounds from dog bites and routine prophylactic use in postoperative settings (that is: for surgically created wounds without complications, where accelerated granulation therapy is not necessary or can be achieved by other available topical wound treatment). Rui-Feng and others (2016) published the results of a randomized controlled trial (RCT) investigating NPWT for serious dog bite wounds; this study found that infection rates were decreased for individuals treated with NPWT compared to sterile dressings (4.0% versus 9.1%, respectively). Due to a lack of additional credible published evidence, NPWT for the use in serious dog bite wounds is not a generally accepted standard of practice. Routine prophylactic NPWT for postoperative care has been evaluated by a number of studies; however, many studies exhibit methodological flaws, including lack of standardized definitions for reporting adverse events or inclusion criteria, publication biases, heterogeneity due to wide ranges of surgical procedures evaluated, and short follow-up (Cagney 2020; Curran, 2019; Fleming, 2018; Galiano, 2018; Gombert, 2020; Hyldig, 2019; Kenney, 2019; Saunders, 2021; Shiroky, 2020; Strugala; 2017; Zwanenburg 2020). Overall evidence for the effectiveness of NPWT on post-operative wound healing compared to standard care remains uncertain (Costa, 2020; De Vries, 2016; De Vries, 2017; Flynn, 2019; Higuera-Rueda, 2021; Karlakki, 2016; Kuo, 2021; Meyer, 2020; O'Neill, 2020; Sexton, 2020; Tuuli, 2020). Norman and colleagues (2020) published the results of a Cochrane systematic review and concluded with moderate-certainty evidence that prophylactic NPWT reduced surgical site infections, however there was low-certainty evidence for the reduction of deaths or wound dehiscence. In addition, the evidence was low or very low for other secondary outcomes evaluated.

Prophylactic NPWT

Bueno-Lledó (2021) published the results of an unblinded single-site RCT involving 146 subjects undergoing surgical repair of inguinal hernia treated with either prophylactic NPWT (n=72) or standard care (n=74). The authors reported that at 30 days there was significantly higher incidence of overall surgical site adverse events, in the control group vs. to the NPWT group (29.8% vs 16.6%, p<0.042), a result mainly driven by a significantly higher surgical site infection occurrence (SSO) rate in the control group vs. the NPWT group (0 vs. 6 cases, p<0.002). There was no difference in postoperative seroma, hematoma, or dehiscence between groups, or difference in hospital length of stay. While the results are promising, they are not widely generalizable given the low power of the trial, the lack of blinding and other methodological factors. The authors conclude that "more prospective studies [...] are needed to effectively evaluate advanced wound care technologies and novel NPWT dressings, which are purported to provide additional benefits to reduce the incidence of SSOs."

Cooper (2022) investigated the use of NPWT in an RCT involving 120 subjects with previously identified risk factors for surgical site complications who underwent direct anterior approach to total hip arthroplasty (n=60 in each group). Overall, surgical site complications were reported in 13.3% of subjects, with 18.3% in control subjects vs. 8.3% NPWT subjects (p=0.107). The majority of the subjects with surgical site complications (9.2% of the overall cohort) also met CDC criteria for superficial surgical site infections, with 9 (15.0%) control group subjects and 2 (3.3%) NPWT subjects (p=0.027). No differences between groups were reported with regard to wound dehiscence (p=0.11), seep surgical site infection (p=0.50), or prolonged drainage (p=0.12).

Svensson-Björk (2022) reported on an RCT investigating the impact of NPWT on surgical site infections in 377 subjects who underwent endovascular aneurysm repair and postoperative treatment with NPWT (n=183) or standard care (n=194) with the primary intent of fascia closure. Bilateral incisions were done in 223 subjects and unilateral incisions were done in 52 subjects. At 90 days post-procedure no significant differences between groups were reported with regard to surgical site infection (p=0.18 in the cohort with bilateral incisions and p=1.0 in those with unilateral incisions). At 1 year similar results were reported (p=0.29 and p=1.0, respectively). The authors concluded that NPWT provided no benefit with regard to surgical site infection post endovascular aneurysm repair.

Lopez-Lopez (2023) reported the results of the PONILITRANS study, a RCT involving 108 subjects who underwent liver transplantation procedures were assigned to postoperative treatment with either prophylactic incisional NPWT (n=54) or standard surgical dressing (n=54). The overall rate of surgical wound infection in the entire study population was 10.2%, with 13% in the control group and 7.4% in the NPWT group (p=034). Furthermore, significant difference between groups was reported with regard to rate of surgical wound-related events (p=0.83), wound hematoma rates (p=0.65), or dehiscence rate (p=0.65). The authors concluded, "The prophylactic use of negative pressure wound therapy on primarily closed incisions did not significantly reduce incisional surgical site infection and surgical site event rates after liver transplantation compared with standard surgical dressings."

Kaçmaz (2023) reported on an RCT involving 50 subjects who underwent colorectal surgery and received post-operative treatment with either prophylactic NPWT (n=24) or standard wound care (n=26). Overall, at the 3 month endpoint 16.7% of subjects in the NPWT group developed surgical site infections vs. 53.8% of control group subjects (p=006). Additionally, the incidence of seroma was significantly greater in the control group (8.3% vs 34.6%, p=0.025). No differences in median length of stay between groups were reported (p=0.153), and no hematomas or wound dehiscence/evisceration were noted. The authors concluded, "This study confirmed that pNPWT effectively helps prevent SWCs in high-risk wounds after open CRC surgery."

Sapci (2023) reported on a similar trial investigating the impact of NPWT on superficial surgical site infections in high-risk, open, reoperative, colorectal surgery. A total of 298 subjects were included (149 in each group). Contrary to the findings of the Kaçmaz study, at 30-days post-surgery the superficial surgical site infection rate was not significantly different between groups (14.1% for controls vs. 9.4% for NPWT; p=0.28). Additionally, no differences between groups were found in 7-day superficial (p=0.28), deep (p>0.99), organ-space (p=0.62) surgical site infections rate, or Clavien-Dindo grade of 30-day postoperative complications (p=0.23) or rates of wound dehiscence (p=0.62). Length of hospital stay was comparable between the groups (6 days vs. 7 day, p=0.78). The authors concluded, "Incisional negative pressure wound therapy was not associated with reduced superficial surgical site infection or overall complication rates in patients undergoing high-risk reoperative colorectal resections"

Ceppa (2023) also reported on an RTC involving 138 subjects undergoing major elective colorectal or hepatopancreatobiliary surgery and receiving postoperative treatment with either NPWT (n=63) or standard of care (n=75). The authors reported no difference between the groups with regard to proportion of subjects with surgical site infections (14% of the NPWT group vs. 17% of the control group, p=0.31). Additionally, there were no significant differences between the groups with regard to superficial incisional infections (9% vs. 11%, p=not reported), deep incisional infections (8% vs. 3%, p=not reported) or organ or space infections (13% vs. 11%, p=0.35). No differences between groups were reported with regard to length of hospital stay (p=0.06) or readmission within 30 days (p=0.77). The authors concluded there was no benefit found for NPWT individuals undergoing major elective colorectal or

hepatopancreatobiliary surgery.

Despite a number of published studies and meta-analysis evaluating use of prophylactic NPWT for postoperative indications, the conflicting outcomes reported data does not support routine use or prophylactic NPWT at this time.

Contraindications

While NPWT is generally safe and well tolerated, complications can include bleeding, infection, pain, and organ damage. Complications are more likely to occur when NPWT is applied to individuals with contraindications to vacuum assisted wound therapy, such as exposed vital structures (for example, organs, blood vessels, vascular grafts), malignancy in the wound, necrotic tissue with eschar, non-enteric and unexplored fistulas, or untreated osteomyelitis.

Authoritative Organization Recommendations

In 2016 the Society for Vascular Surgery, the American Podiatric Medical Association, and the Society for Vascular Medicine released joint recommendations related to the management of diabetic foot wounds (Hingorani, 2016). In this document, they provide the following recommendation: "We suggest 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 4 to 8 weeks of therapy (Grade 2B)."

Definitions

Dehisced wounds: A condition where a wound has a premature opening or splitting along natural or surgical suture lines due to improper healing.

Eschar: A dry scab that forms on skin that has been burned or exposed to corrosive agents.

Group 2 or 3 support surfaces: Two groups within the three classifications of specialized pressure reducing bed types available as a preventive measure for bedsores. The classification system is as follows:

Group 1 - Pressure reducing mattress overlays. These overlays may be filled with air, water, foam or gel and are intended for placement over a standard mattress

Group 2 - Special mattresses alone or fully integrated into a bed. These mattresses may be filled with air, water, foam or gel and are intended as a replacement for a standard mattress

Group 3 - Air Fluidized Beds. These are devices that employ the circulation of filtered air through silicone coated ceramic beads that create the characteristics of fluid, creating a sensation of floating

Mediastinitis: A condition characterized by inflammation of the cavity that holds the heart and other organs.

Neuropathic ulcer: An ulcer resulting from the loss of sensation (i.e., pain, touch, stretch) as well as protective reflexes, due to loss of nerve supply to a body part.

Post sternotomy: The period of time immediately following any surgery where the sternum or breastbone is opened to gain access to the chest cavity.

Pressure ulcer (National Pressure Injury Advisory Panel, 2019): A pressure injury is localized damage to the skin and/or underlying soft 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.

Pressure ulcer stages:

Pressure Injury:

A pressure injury is localized damage to the skin and/or underlying soft 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.

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.

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 an ischemic limb or the heel(s) should not be removed.

Deep Tissue Pressure Injury:

Persistent non-blanchable deep red, maroon or purple discoloration. Intact or non-intact 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 DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

Medical Device Related Pressure Injury:

This describes an etiology. Medical device related pressure injuries result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.

Mucosal Membrane Pressure Injury:

Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these injuries cannot be staged.

Vacuum assisted wound therapy: A type of medical therapy that involves the use of suction (negative pressure) underneath airtight wound dressings to promote the healing of open wounds that have resisted previous treatments.

References

Peer Reviewed Publications:

- Armstrong DG, Lavery LA.; Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet. 2005; 366(9498):1704-1710.
- 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; 19(2):173-180.
- 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 Rep Reg. 2012; 20(3):332-341.
- 4. Baharestani MM. Use of negative pressure wound therapy in the treatment of neonatal and pediatric wounds: a retrospective examination of clinical outcomes. Ostomy Wound Manage. 2007; 53(6):75-85.
- Baillot R, Cloutier D, Montalin L, et al. Impact of deep sternal wound infection management with vacuum-assisted closure therapy followed by sternal osteosynthesis: a 15-year review of 23,499 sternotomies. Eur J Cardiothorac Surg. 2010; 37(4):880-887.
- Blume PA, Walters J, Payne W, et al. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers: a multicenter randomized controlled trial. Diabetes Care 2008; 31(4):631-636.
- 7. Bradbury S, Walkley N, Ivins N, Harding K. Clinical evaluation of a novel topical negative pressure device in promoting healing in chronic wounds. Adv Wound Care (New Rochelle). 2015; 4(6):346-357.
- 8. Bueno-Lledó J, Franco-Bernal A, Garcia-Voz-Mediano et al. Prophylactic single-use negative pressure dressing in closed surgical wounds after incisional hernia repair: a randomized, controlled trial. Ann Surg. 2021; 273(6):1081-1086.
- 9. Cagney D, Simmons L, O'Leary DP, et al. The efficacy of prophylactic negative pressure wound therapy for closed incisions in breast surgery: a systematic review and meta-analysis. World J Surg. 2020; 44(5):1526-1537.
- Caniano DA, Ruth B, Teich S. Wound management with vacuum-assisted closure: experience in 51 pediatric patients. J Pediatr Surg. 2005; 40(1):128-152.
- Carrano FM, Maroli A, Carvello M, et al Negative-pressure wound therapy after stoma reversal in colorectal surgery: a randomized controlled trial. BJS Open. 2021; 5(6):zrab116.
- Ceppa EP, Kim RC, Niedzwiecki D, et al.; Closed Incision Negative Pressure Therapy (ciNPT) Investigators. Closed incision negative pressure therapy to reduce surgical site infection in high-risk gastrointestinal surgery: a randomized controlled trial. J Am Coll Surg. 2023; 236(4):698-708.
- 13. Chen B, Hao F, Yang Y, et al. Prophylactic vacuum sealing drainage (VSD) in the prevention of postoperative surgical site infections in pediatric patients with contaminated laparotomy incisions. Medicine (Baltimore), 2017; 96(13):e6511.
- 14. Cooper HJ, Santos WM, Neuwirth AL, et al. Randomized controlled trial of incisional negative pressure following high-risk direct anterior total hip arthroplasty. J Arthroplasty. 2022; 37(8S):S931-S936.
- Costa ML, Achten J, Bruce J, et al.; UK WOLLF Collaboration. Effect of negative pressure wound therapy vs standard wound management on 12-month disability among adults with severe open fracture of the lower limb: the WOLLF randomized clinical trial. JAMA. 2018; 319(22):2280-2288.
- Costa ML, Achten J, Knight R, et al.; WHIST Trial Collaborators. Effect of incisional negative pressure wound therapy vs standard wound dressing on deep surgical site infection after surgery for lower limb fractures associated with major trauma: the WHIST randomized clinical trial. JAMA. 2020; 323(6):519-526.
- 17. Cuomo R, Grimaldi L, Nisi G, et al. Ultraportable devices for negative pressure wound therapy: first comparative analysis. J Invest Surg. 2021 Mar; 34(3):335-343.
- 18. Cuomo R, Nisi G, Grimaldi L, et al. Use of ultraportable vacuum therapy systems in the treatment of venous leg ulcer. Acta Biomed. 2017; 88(3):297-301.
- Curran T, Alvarez D, Pastrana Del Valle J, et al. Prophylactic closed-incision negative-pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. Colorectal Dis. 2019; 21(1):110-118.
- De Franzo AJ, Argenta LC, Marks MW, et al. The use of vacuum-assisted closure therapy for the treatment of lower extremity wounds with exposed bone. Plast Reconstr Surg. 2001; 108(5):1184-1191.
- 21. De Vries FEE, Atema JJ, Lapid O, et al. Closed incision prophylactic negative pressure wound therapy in patients undergoing major complex abdominal wall repair. Hernia. 2017; 21(4):583-589.
- 22. De Vries FEE, Wallert ED, Solomkin JS, et al. A systematic review and meta-analysis including GRADE qualification of the risk of surgical site infections after prophylactic negative pressure wound therapy compared with conventional dressings in clean and contaminated surgery. Medicine (Baltimore). 2016; 95(36):e4673.
- Doss M, Martens S, Wood JP, et al. Vacuum-assisted suction drainage versus conventional treatment in the management of poststernotomy osteomyelitis. Eur J Cardiothorac Surg. 2002; 22(6):934-938.
- 24. Eginton MT, Brown KR, Seabrook GR, et al. A prospective randomized evaluation of negative-pressure wound dressings for diabetic foot wounds. Ann Vasc Surg. 2003; 17(6):645-649.
- 25. Fleming CA, Kuteva M, O'Hanlon K, et al. Routine use of PICO dressings may reduce overall groin wound complication rates following peripheral vascular surgery. J Hosp Infect. 2018; 99(1):75-80.
- 26. Flynn J, Choy A, Leavy K, et al. Negative pressure dressings (PICOTM) on laparotomy wounds do not reduce risk of surgical

- site infection. Surg Infect (Larchmt). 2020; 21(3):231-238.
- 27. Fong KD, Hu D, Eichstadt SL, et al. Initial clinical experience using a novel ultraportable negative pressure wound therapy device. Wounds. 2010; 22(9):230–236.
- 28. Ford CN, Reinhard ER, Yeh D, et al. Interim analysis of a prospective, randomized trial of vacuum-assisted closure versus the healthpoint system in the management of pressure ulcers. Ann Plast Surg. 2002; 49(1):55-61.
- 29. Gabriel A, Heinrich C, Shores J, et al. Outcomes of vacuum-assisted closure for the treatment of wounds in a paediatric population: case series of 58 patients. J Plast Reconstr Aesthet Surg. 2009; 62(11):1428-1436.
- 30. 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; 10(4):418-424.
- 31. Galiano RD, Hudson D, Shin J, et al. Incisional negative pressure wound therapy for prevention of wound healing complications following reduction mammaplasty. Plast Reconstr Surg Glob Open. 2018; 6(1):e1560.
- 32. Garner GB, Ware DN, Cocanour CS, et al. Vacuum-assisted wound closure provides early fascial reapproximation in trauma patients with open abdomens. Am J Surg. 2001; 182(6):630-638.
- 33. Gombert A, Dillavou E, D'Agostino R Jr, et al. A systematic review and meta-analysis of randomized controlled trials for the reduction of surgical site infection in closed incision management versus standard of care dressings over closed vascular groin incisions. Vascular. 2020; 28(3):274-284.
- 34. Gupta R, Darby GC, Imagawa DK. Efficacy of negative pressure wound treatment in preventing surgical site infections after Whipple procedures. Am Surg. 2017; 83(10):1166-1169.
- 35. Hersh RE, Jack JM, Dahman MI, et al. The vacuum-assisted closure device as a bridge to sternal wound closure. Ann Plast Surg. 2001; 46(3):250-254.
- 36. Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, et al. The effectiveness of closed-incision negative-pressure therapy versus silver-impregnated dressings in mitigating surgical site complications in high-risk patients after revision knee arthroplasty: the PROMISES randomized controlled trial. J Arthroplasty. 2021; 36(7S):S295-S302.e14.
- 37. Hudson DA, Adams KG, Huyssteen AV, et al. Simplified negative pressure wound therapy: clinical evaluation of an ultraportable, no-canister system. Int Wound J. 2015; 12(2):195-201.
- 38. Hyldig N, Vinter CA, Kruse M, 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; 126(5):628-635.
- 39. Kaçmaz HY, Baser M, Sozuer EM. Effect of prophylactic negative-pressure wound therapy for high-risk wounds in colorectal cancer surgery: a randomized controlled trial. Adv Skin Wound Care. 2022; 35(11):597-603.
- 40. Karlakki SL, Hamad AK, Whittall C, et al. Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: a randomised controlled trial. Bone Joint Res. 2016; 5(8):328-337.
- 41. Keeney JA, Cook JL, Clawson SW, et al. Incisional negative pressure wound therapy devices improve short-term wound complications, but not long-term infection rate following hip and knee arthroplasty. J Arthroplasty. 2019; 34(4):723-728.
- 42. Kirsner R, Dove C, Reyzelman A, et al. A prospective, randomized, controlled clinical trial on the efficacy of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of chronic ulcers of the lower extremities. Wound Repair Regen. 2019; 27(5):519-529.
- 43. Kirsner RS, Zimnitsky D, Robinson M. A prospective, randomized, controlled clinical study on the effectiveness of a single-use negative pressure wound therapy system, compared to traditional negative pressure wound therapy in the treatment of diabetic ulcers of the lower extremities. Wound Repair Regen. 2021; 29(6):908-911.
- 44. Kuo FC, Hsu CW, Tan TL, et al. Effectiveness of different wound dressings in the reduction of blisters and periprosthetic joint infection after total joint arthroplasty: a systematic review and network meta-analysis. J Arthroplasty. 2021; 36(7):2612-2629.
- 45. León Arellano M, Barragán Serrano C, Guedea M, et al. Surgical wound complications after colorectal surgery with single-use negative-pressure wound therapy versus surgical dressing over closed incisions: a randomized controlled trial. Adv Skin Wound Care. 2021; 34(12):657-661.
- 46. Lerman B, Oldenbrook L, Eichstadt SL, et al. Evaluation of chronic wound treatment with the SNAP wound care system versus modern dressing protocols. Plast Reconstr Surg. 2010; 126(4):1253-1261.
- 47. Li RG, Ren GH, Tan XJ, et al. Free flap transplantation combined with skin grafting and vacuum sealing drainage for repair of circumferential or sub-circumferential soft-tissue wounds of the lower leg. Med Sci Monit. 2013; 19:510-517.
- 48. Llanos S, Danilla S, Barraza C, et al. Effectiveness of negative pressure closure in the integration of split thickness skin grafts: a randomized, double-masked, controlled trial. Ann Surg. 2006; 244(5):700-705.
- 49. Lopez-Lopez V, Hiciano-Guillermo A, Martinez-Alarcon L, et al. Postoperative negative-pressure incision therapy after liver transplant (PONILITRANS study): A randomized controlled trial. Surgery. 2023;173(4):1072-1078.
- 50. Marston WA, Armstrong DG, Reyzelman AM, Kirsner RS. A multicenter randomized controlled trial comparing treatment of venous leg ulcers using mechanically versus electronically powered negative pressure wound therapy. Adv Wound Care (New Rochelle). 2015; 4(2):75-82.
- 51. Meyer J, Roos E, Abbassi Z, et al. Prophylactic negative-pressure wound therapy prevents surgical site infection in abdominal surgery: an updated systematic review and meta-analysis of randomized controlled trials and observational studies. Clin Infect Dis. 2021; 73(11):e3804-e3813.
- 52. Moisidis E, Heath T, Boorer C, et al. A prospective, blinded, randomized, controlled clinical trial of topical negative pressure use in skin grafting. Plast Reconstr Surg. 2004; 114(4):917-922.
- 53. Mouës CM, van den Bemd GJ, Heule F, Hovius SE. Comparing conventional gauze therapy to vacuum-assisted closure wound therapy: a prospective randomised trial. J Plast Reconstr Aesthet Surg. 2007; 60(6):672-681.
- 54. Moues CM, Vos MC, van den Bemd GJ, et al. Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. Wound Repair Regen. 2004; 12(1):11-17.
- 55. O'Connor J, Kells A, Henry S, Scalea T. Vacuum-assisted closure for the treatment of complex chest wounds. Ann Thorac Surg. 2005; 79(4):1196-1200.
- O'Neill CH, Martin RCG 2nd. Negative-pressure wound therapy does not reduce superficial SSI in pancreatectomy and hepatectomy procedures. J Surg Oncol. 2020; 122(3):480-486.
- 57. Pellino G, Sciaudone G, Candilio G, et al. Effects of a new pocket device for negative pressure wound therapy on surgical wounds of patients affected with Crohn's disease: a pilot trial. Surg Innov. 2013; 21(2):204-212.
- 58. Peterson AT, Bakaysa SL, Driscoll JM, et al. Randomized controlled trial of single-use negative-pressure wound therapy dressings in morbidly obese patients undergoing cesarean delivery. Am J Obstet Gynecol MFM. 2021; 3(5):100410.
- 59. Petkar KS, Dhanraj P, Kingsly PM, et al. A prospective randomized controlled trial comparing negative pressure dressing and conventional dressing methods on split-thickness skin grafts in burned patients. Burns. 2011; 37(6):925-929.
- 60. Rui-Feng C, Li-Song H, Ji-Bo Z, et al. Negative pressure wound therapy for serious dog bites of extremities: a prospective randomized trial. Am J Emerg Med. 2016; 34(6):1006-1010.
- 61. Saaiq M, Hameed-Ud-Din, Knan MI, Chaudhery SM. Vacuum-assisted closure therapy as a pretreatment for split thickness skin grafts. J Coll Physicians Surg Pak. 2010; 20(10):675-679.
- 62. Sapci I, Camargo M, Duraes L, et al. Effect of incisional negative pressure wound therapy on surgical site infections in highrisk reoperative colorectal surgery: a randomized controlled trial. Dis Colon Rectum. 2023; 66(2):306-313.
- 63. 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.
- 64. Seidel D, Diedrich S, Herrle F, et al. Negative pressure wound therapy vs conventional wound treatment in subcutaneous abdominal wound healing impairment the SAWHI randomized clinical trial. JAMA Surg. 2020; 155(6):469-478.
- 65. Selvaggi F, Pellino G, Sciaudone G, et al. New advances in negative pressure wound therapy (NPWT) for surgical wounds of patients affected with Crohn's disease. Surg Technol Int. 2014; 24:83-89.
- 66. Sexton F, Healy D, Keelan S, et al. A systematic review and meta-analysis comparing the effectiveness of negative-pressure wound therapy to standard therapy in the prevention of complications after vascular surgery. Int J Surg. 2020; 76:94-100.
- 67. Shiroky J, Lillie E, Muaddi H, et al. The impact of negative pressure wound therapy for closed surgical incisions on surgical site infection: A systematic review and meta-analysis. Surgery. 2020; 167(6):1001-1009.
- 68. Smid MC, Dotters-Katz SK, Grace M, et al. Prophylactic negative pressure wound therapy for obese women after cesarean delivery: a systematic review and meta-analysis. Obstet Gynecol. 2017; 130(5):969-978.
- 69. Stannard JP, Volgas DA, McGwin G 3rd, et al. Incisional negative pressure wound therapy after high-risk lower extremity fractures. J Orthop Trauma. 2012; 26(1):37-42.
- Stannard JP, Volgas DA, Stewart R, et al. Negative pressure wound therapy after severe open fractures: a prospective randomized study. J Orthop Trauma. 2009; 23(8):552-557.
- 71. Strugala V, Martin R. Meta-analysis of comparative trials evaluating a prophylactic single-use negative pressure wound therapy system for the prevention of surgical site complications. Surg Infect (Larchmt). 2017; 18(7):810-819.
- 72. Svensson-Björk R, Hasselmann J, Asciutto G, et al. Negative pressure wound therapy for the prevention of surgical site infections using fascia closure after EVAR-A randomized trial. World J Surg. 2022; 46(12):3111-3120.
- 73. Tuuli MG, Liu J, Tita ATN, et al. Effect of prophylactic negative pressure wound therapy vs standard wound dressing on surgical-site infection in obese women after cesarean delivery: a randomized clinical trial. JAMA. 2020; 324(12):1180-1189.
- 74. Visser R, Milbrandt K, Lum Min S, et al. Applying vacuum to accomplish reduced wound infections in laparoscopic pediatric surgery. J Pediatr Surg. 2017; 52(5):849-852.
- 75. Yang C, Wang S, Li CC, et al. A high-vacuum wound drainage system reduces pain and length of treatment for pediatric soft tissue abscesses. Eur J Pediatr. 2017; 176(2):261-267.
- 76. Zwanenburg PR, Tol BT, Obdeijn MC, et al. Meta-analysis, meta-regression, and GRADE assessment of randomized and nonrandomized studies of incisional negative pressure wound therapy versus control dressings for the prevention of postoperative wound complications. Ann Surg. 2020; 272(1):81-91.

Government Agency, Medical Society, and Other Authoritative Publications:

- 1. Dumville JC, Land L, Evans D, Peinemann F. Negative pressure wound therapy for treating leg ulcers. Cochrane Database Syst Rev. 2015; (7):CD011354.
- Dumville JC, Munson C. Negative pressure wound therapy for partial-thickness burns. Cochrane Database Syst Rev. 2014; (12):CD006215.
- 3. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016; 63(2 Suppl):3S-21S.
- 4. Iheozor-Ejiofor Z, Newton K, Dumville JC, Costa ML, Norman G, Bruce J. Negative pressure wound therapy for open traumatic wounds. Cochrane Database Syst Rev. 2018; 7:CD012522.
- Liu Z, Dumville JC, Hinchliffe RJ, et al. Negative pressure wound therapy for treating foot wounds in people with diabetes mellitus. Cochrane Database Syst Rev. 2018; 10(10):CD010318
- National Pressure Ulcer Advisory Panel. Pressure Injury Stages Revised by NPUAP. January 24, 2017. Available at: https://npuap.org/page/PressureInjuryStages. Accessed on August 7, 2023.
- National Pressure Injury Advisory Panel (NPIAD). Prevention and treatment of pressure ulcers: clinical practice guideline. 3^{cl} edition. 2019. Available at: https://internationalguideline.com/2019. Accessed on August 7, 2023.
- 8. Norman G, Goh EL, Dumville JC, et al. Negative pressure wound therapy for surgical wounds healing by primary closure. Cochrane Database Syst Rev. 2020; 6(6):CD009261.
- Shi J, Gao Y, Tian J, et al. Negative pressure wound therapy for treating pressure ulcers. Cochrane Database Syst Rev. 2023; 26:5(5):CD011334.
- U.S. FDA Safety Communication: UPDATE on Serious Complications Associated with Negative Pressure Wound Therapy Systems. February 2, 2011.

Index

ABThera[™] Open Abdomen Negative Pressure Therapy

ActiV.A.C.® Therapy System

Avelle Negative Pressure Wound Therapy System

Engenex® Advanced NPWT System

Exusdex[™] Wound Drainage Pump

InfoV.A.C.® Therapy System

Invia Liberty Wound Therapy

NANOVA Therapy System

Nexa Negative Pressure Wound Therapy System

PICO Single Use Negative Pressure Wound Therapy System

Prevena[™] Incision Management System

Prodigy[™] NPWT System (PMS-800 and PMS-800V)

PRO-I[™]

PRO-II[™]

 $\mathsf{PRO}\text{-}\mathsf{III}^\mathsf{TM}$

RENASYS EZ[™]

RENASYS GO[™]

SNAP Wound Care Device

SVED® Wound Treatment Systems

UNO Negative Pressure Wound Therapy System

V.A.C.

V.A.C. ATS®

V.A.C. Freedom[®]

VAC Simplicity [™]

V.A.C.Ulta [™]

V.A.C.Via Negative Pressure Wound Therapy System VAWC Device

Vacuum Assisted Wound Closure System

Venturi [™] Negative Pressure Wound Therapy

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History		
Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Discussion/General Information and References sections.
Reviewed	08/11/2022	MPTAC review. Updated Discussion/General Information and References sections.
Revised	08/12/2021	MPTAC review. Removed note from Clinical Indications, added prophylactic use in postoperative setting to NMN statement. Updated Discussion/General Information and References sections.
New	05/13/2021	MPTAC review. Initial document development. Moved content of DME.00009 Vacuum Assisted Wound Therapy in the Outpatient Setting to a new clinical utilization management guideline document with the same title. Removed non-electrically powered vacuum assisted wound therapy from the Not Medically Necessary Clinical Indications.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only - American Medical Association