

# Negative Pressure Wound Therapy

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## Introduction

Negative pressure wound therapy (NPWT) devices are addressed by this guideline.

## Criteria

### Initial Rental for Acute Wounds

A negative pressure wound therapy (NPWT) pump (HCPCS E2402) and supplies (HCPCS A6550, A7000) are indicated for an acute surgical (e.g., dehiscence) or traumatic wound (e.g., pre-operative flap or graft) when **both** of the following apply:

A wound therapy program has been tried including **all** of the following, and there are no measurable signs of improved healing:

- The wound has been assessed, measured, and described.
- Topical dressings appropriate for wound type have been applied.
- Debridement has been performed to remove necrotic tissue (if present).
- Treatment or intervention to correct any infection and/or underlying condition that may hinder the healing process has been performed (if needed).

Negative pressure wound therapy is not indicated when **any** of the following are present:

- Untreated osteomyelitis near the wound.
- Necrotic tissue with slough or eschar present, if debridement has not been attempted.
- Cancer present in the wound.
- Wounds with fistulae to an organ or body cavity in the wound.
- Exposed nerves or vascular structures.

### Initial Rental for Non-healing, Chronic Wounds

A negative pressure wound therapy (NPWT) pump (HCPCS E2402) and supplies (HCPCS A6550, A7000) are indicated for a non-healing, chronic wound, when **all** of the following apply:

Wound therapy has been tried, including **all** of the following, and there are no measurable signs of improved healing:

- The wound has been assessed, measured, and described.

- Topical dressings appropriate for wound type have been applied.
- Debridement has been performed to remove necrotic tissue (if present).
- Treatment or intervention to correct any infection and/or underlying condition that may hinder the healing process has been performed (if needed).

There is documentation of a non-healing, chronic wound with **any** of the following:

- Stage 3 or 4 pressure injury with documentation of **all** of the following:
  - Repositioning and mobilization program for offloading of pressure has been tried.
  - Management of moisture and incontinence has been performed (if present).
  - Use of a pressure-reducing support system has been tried or ruled out.
- Diabetic ulcer with documentation of **all** of the following:
  - The individual has ongoing care of diabetes.
  - Use of an off-loading, pressure-reducing strategy has been tried, which may include **any** of the following:
    - crutches, walkers, wheelchairs, custom shoes, shoe modifications, custom diabetic inserts, custom relief orthotic walkers, diabetic boots, forefoot and heel relief shoes, or total contact casts, or various types of specialized, protective footwear.
  - Venous ulcer with documentation of **all** of the following:
    - Compression bandages and/or garments have been applied.
    - Leg elevation has been tried.
    - Regular exercise has been tried.
  - Arterial ulcer with documentation of the following:
    - Establishment of adequate circulation to the wound site has been performed.
  - Other complex, chronic wound.

NPWT is not indicated when **any** of the following are present:

- Untreated osteomyelitis near the wound.
- Necrotic tissue with slough or eschar present, if debridement has not been attempted.
- Cancer present in the wound.
- Wounds with fistulae to an organ or body cavity in the wound.
- Exposed nerves or vascular structures.

### Initial Rental

- Initial rental period of one month (30 days).

### Continued Rental

- Continued use is provided for one month (30 day) increments. Continued use of a negative pressure wound therapy (NPWT) pump (HCPCS E2402) and supplies (HCPCS A6550, A7000) are indicated when **all** of the following apply:

- There is documentation that wound healing is progressing.
- There is monthly documentation of wound length, width, and depth.
- There is monthly documentation of proper use of the device and continued benefit.

### Rental Period Exceeding Four (4) Months

Use of a negative pressure wound therapy (NPWT) pump (HCPCS E2402) and supplies (HCPCS A6550, A7000) for a month exceeding four months in total duration is indicated when **all** of the following apply:

- There is monthly documentation that wound healing is progressing.
- There is monthly documentation of wound length, width and depth.
- There is monthly documentation of proper use of the device and continued benefit.
- There is monthly documentation of specific and detailed information to explain the continuing problems with the wound and what additional measures are being undertaken to address those problems and promote healing.
- There is monthly documentation of why a switch to alternative treatments alone is not possible.

### Discontinuation

- Continued coverage of a negative pressure wound therapy (NPWT) pump and supplies is not indicated for wounds and ulcers described in this guideline when there is documentation of **any** of the following:
  - Criteria for continued rental of the NPWT pump and supplies has not been met.
  - There is no measurable degree of wound healing improvement occurring in either surface area (length times width) or depth of the wound over the prior month.
  - In the judgment of the treating practitioner, adequate wound healing has occurred to the degree that NPWT may be discontinued.

### Supplies

- A maximum of 15 **dressing kits** (HCPCS A6550) per wound, per month is indicated unless there is documentation that the wound size requires more than one dressing kit for each dressing change.
- A maximum of 10 **canister sets** (HCPCS A7000) per month is indicated unless there is documentation evidencing a large volume of drainage (e.g., greater than 90 ml of exudate per day).

### Pediatric Use

"The safety and effectiveness of negative pressure wound therapy (NPWT) systems in newborns, infants, and children has not been established at this time, and currently,

there are no NPWT systems cleared for use by the FDA in these populations" (FDA, 2011).

### Additional Information

- The rental period for initial and continued use of a negative pressure wound therapy (NPWT) pump is limited to 30 days per request.
- A licensed health care practitioner, for the purposes of this guideline, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The treating practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.
- Assessment, measurement and description of wound(s) may include the type of wound; location; color; size (length, width, and depth); description of exudate; signs of infection (e.g., erythema, edema, odor); evidence of healing (granulation or epithelization); presence of sinus tracts, tunneling, undermining, or exposed structures; type and color of devitalized tissue (e.g., slough or eschar); and/or dressing type.

### Not Covered

- Single use, disposable NPWT devices are not considered durable medical equipment (DME). Examples may include but are not limited to: Solventum SNAP®, Smith and Nephew PICO®, and Solventum V.A.C.® Via.
- Other suction pump systems (HCPSC K0743, K0744, K0745, and K0746) may also be used to remove exudate from a wound. These systems are not discussed in this guideline.

### Definitions

**Negative pressure wound therapy (NPWT)** involves applying continuous or intermittent negative (subatmospheric) pressure to a sealed dressing positioned in a wound cavity or over a flap, graft, or surgical incision. A resulting vacuum effect draws the edges of the wound together, promotes new tissue growth while providing a moist environment, and assists with drainage of wound exudate.

A **chronic ulcer**, or non-healing wound, either does not progress through an orderly and timely sequence of repair, or the repair process is impaired and does not reach resolution.

The **National Pressure Injury Advisory Panel (NPIAP)** provides a method for **classification of pressure injuries**. The system is supported by the Wound Ostomy Continence Nurses (WOCN) Society:

- **Stage 1 pressure injury:** 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. No purple or maroon discoloration, as these may indicate deep tissue pressure injury.
- **Stage 2 pressure injury:** Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may present as an intact or ruptured serum-filled blister. Adipose (fat) and deeper tissue 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 including incontinence associated dermatitis, intertriginous dermatitis, medical adhesive related skin injury, or traumatic wounds (e.g., skin tears, burns, abrasions).
- **Stage 3 pressure injury:** Full-thickness skin loss, in which adipose (fat) tissue is visible in the ulcer, and granulation tissue and rolled wound edges are often present. Slough 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 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 with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage, or bone. Slough or eschar may be visible. Rolled wound edges, undermining, 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 full-thickness pressure injury:** 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 (e.g., dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.
- **Deep tissue pressure injury (DTPI):** Intact or nonintact skin with localized area of persistent non-blanchable deep red, maroon, or 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 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 (i.e., unstageable, stage 3, or stage 4). DTPI is not used to describe vascular, traumatic, neuropathic, or dermatologic conditions.

**Peripheral artery disease (PAD)** is a circulatory problem in which narrowed arteries reduce blood flow to limbs, resulting in compromised blood flow to the distal tissue and failure to keep up with oxygen demands. Physiologic testing for PAD defines the severity and extent of disease and helps determine wound healing potential. Studies may include the following: ankle-brachial index (ABI), toe-brachial index (TBI), segmental limb pressures, pulse volume recordings, exercise testing, digit plethysmography, and/or transcutaneous oxygen measurements.

**Arterial ulcers**, or ischemic ulcers, occur most often on the extremities. Poor perfusion starves the overlying tissues of oxygen and nutrients, causing tissue death and open wounds. These wounds are painful and often feature ragged borders, a dry base, and pale or necrotic centers.

**Diabetic ulcers** are a common complication of advanced diabetes mellitus, and most often occur in the feet. The chronic hyperglycemia of diabetes mellitus can lead to microvascular complications, including diabetic neuropathy and peripheral vascular disease. In diabetic neuropathy, an individual may experience numbness in the distal extremities and a lack of protective sensation, which can lead to injuries that may go unnoticed by the individual, leading to infection.

**Venous stasis ulcers** may develop due to poor venous circulation in the extremities, often due to impaired valve functioning, blood clots, or venous hypertension. These wounds often feature hard and discolored skin, edema, and/or pus or fluid.

**Progression of wound healing** may include measurable signs such as: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and/or decrease in amount of necrotic tissue.

## Evidence Discussion

### Purpose of the technology /description of device

Negative pressure wound therapy (NPWT) systems consist of an open-pore polyurethane ether foam sponge, semi-occlusive adhesive cover, fluid collection system, and suction pump. The foam sponge is placed within the wound. It is then covered by the semi-occlusive adhesive dressing. A small hole is cut in the adhesive dressing over the foam sponge. Tubing that is attached to an adhesive disk is placed over the hole in the adhesive dressing. Continuous or intermittent suction applied through the tube places negative pressure on the wound bed, and causes fluid to flow out of the wound and into the fluid collection system.

NPWT accelerates wound healing through direct and indirect effects. The semipermeable dressing of the negative pressure system maintains a moist and warm environment that is stable and conducive to wound healing. The closed system generates a pressure gradient between the wound and suction canister that promotes

fluid transport, first from the wound bed, and then from the interstitial space, reducing wound edema. Thus, fluid is removed through the application of pressure. The increased wound surface pressure alters the blood flow, diminishes the inflammatory response, and alters the bacterial burden.

NPWT has been applied to a wide range of clinical situations, including: following abdominal surgery, following surgical debridement of acute or chronic wounds (e.g., orthopedic, necrotizing infection, pressure ulcer), diabetic foot ulcers, reconstructive surgery (e.g., burns, skin graft, muscle flap), and prophylactically to prevent surgical wound infection.

NPWT dressings are changed less frequently (e.g., every two to five days) compared to traditional wound care therapy, and anticipated pain can be managed preemptively. Compared with other forms of wound dressing, NPWT is easier to tailor and maintain in position. As a result, NPWT may allow less complex modes of reconstructive surgery.

From the individual's perspective, a disadvantage of NPWT is the need to carry the portable pump. NPWT systems are more expensive than traditional wound dressings. However, the overall cost of wound care depends upon the frequency of dressing changes, need for skilled nursing care, and duration of treatment. Complications can include bleeding, infection, pain, organ damage, and possibly death. Such complications are most likely to occur when NPWT is applied to individuals whose wounds have necrotic tissue or exposed vital structures (e.g., organs, blood vessels, vascular grafts).

NPWT should not be used when exposed vital structures or malignant tissue are present. In the presence of exposed organs, blood vessels, or vascular grafts, NPWT increases the risk for tissue erosion, which can lead to enteric fistula or hemorrhage. NPWT is generally avoided until an intervening granulation layer, tissue flap, or graft provides coverage. As with normal tissues, growth of malignant tissue is promoted in the presence of sub-atmospheric pressure. Malignant tissue is also more friable and prone to bleeding. Other potential contraindications to NPWT include ischemic wounds, ongoing infection, necrotic tissue, fragile skin, and adhesive allergy.

## Medical Background

Modern negative pressure wound therapy was developed during the Soviet-Afghanistan war in the 1980s, and later at Wake Forest University School of Medicine in the 1990s. The KCI V.A.C.® therapy system was introduced in 1995. KCI later merged with 3M, and V.A.C.® therapy device manufacturing was then spun off from 3M under the new Solventum umbrella in 2024. Since 1995, additional innovations have been made with the foam used (e.g., GranuFoam™ (polyurethane reticulated open-cell foam, ROCF), GranuFoam Silver™ (ROCF impregnated with silver)), and with the ability to instill solutions into the wound bed through the V.A.C.® system. Instillation through the V.A.C.® system is usually used for wound irrigation and cleaning, but can also be used for administration of topical antibiotics.

As of 2019, the United States Food and Drug Administration (FDA) has reclassified NPWT systems from Class III devices to Class II devices with special controls (FDA, 2021). Manufacturers of Class II devices are required to provide premarket notification with a reasonable assurance of device safety and effectiveness.

## Literature Review

### Management of acute (surgical, traumatic) wounds:

- Zens et al. (2020) conducted a meta-analysis to compare the benefits and harms of negative pressure wound therapy (NPWT) with standard wound therapy (SWT) in patients with wounds healing by secondary intention. The results of the study demonstrated some advantages of NPWT with regard to wound closure and hospital stay; however, the data showed no advantages or disadvantages of NPWT versus SWT for mortality, adverse events, amputation, pain, or health-related quality of life. In addition, the authors noted that publication bias was an important consideration in this analysis, and thus, the authors downgraded the conclusions of the study. In summary, the authors reported low-quality evidence that NPWT improved wound healing and decreased the number of days to healing compared to SWT.
- Haidari et al. (2021) performed a systematic review to assess the use of negative pressure wound therapy (NPWT) in the management of fracture-related infection (FRI) with a focus on recurrence rate, the detection of new pathogens at subsequent dressing changes, and time to wound healing. The authors noted that in acute open traumatic wounds with fractures, NPWT was postulated to prevent ongoing contamination of the wound and help maintain a moist environment. The authors identified eight studies that met inclusion criteria. The authors reported that all eight studies reported an overall infection recurrence of FRI treated with NPWT, which ranged from 2.8% to 34.9%. Six studies described wound healing time, varying from two to seven weeks. One study reported newly detected pathogens in 23% of the included patients, and three studies did not find new pathogens. The authors noted that based on differences between individual study designs and inherent sources of study bias, there was insufficient evidence to determine the effectiveness of NPWT on wound infection, infection recurrence rate, time to wound healing, time to surgery for definitive wound closure, health-related quality of life, or pain. However, the authors noted that NPWT may have been safe for a few days as temporary soft tissue coverage until definitive soft tissue management. Moreover, additional comparative studies between NPWT and early wound closure in FRI patients were recommended.
- A 2020 multicenter, randomized clinical trial conducted by Seidel and colleagues evaluated the effectiveness and safety of negative pressure wound therapy (NPWT) for subcutaneous abdominal wound healing impairment (SAWHI) after surgery. Five hundred seven participants with SAWHI after surgery without fascia dehiscence were randomly assigned to NPWT or conventional wound treatment. The primary outcome was time until wound closure (delayed primary closure or by secondary intention)

within 42 days. Secondary outcomes included wound closure rate within 42 days, quality of life, pain, and patient satisfaction. The mean time to wound closure was significantly shorter in the NPWT arm (36.1 days) compared to the conventional wound treatment (CWT) arm (39.1 days). The wound closure rate within 42 days was significantly higher with the NPWT arm (35.9%) than with the CWT arm (21.5%). However, in the therapy-compliant population, the risk for wound-related adverse events was higher in the NPWT arm. The authors concluded that NPWT was an effective treatment option for SAWHI after surgery; however, in this study, NPWT caused more wound-related adverse events.

- Stannard et al. (2012) conducted a randomized clinical trial to investigate negative pressure wound therapy (NPWT) to prevent wound dehiscence and infection after high-risk lower extremity trauma. Two hundred forty-nine patients with high-risk fracture types (tibial plateau, pilon, calcaneus) requiring surgical stabilization were randomized to NPWT or standard postoperative dressings (control). The results of the study demonstrated a total of 23 infections in the control group and 14 infections in the group that received NPWT. The relative risk of developing an infection was 1.9 times higher in control patients than in patients treated with NPWT. The authors reported a decreased incidence of wound dehiscence and total infections after high-risk fractures when individuals had NPWT applied to their surgical incisions after closure. Moreover, there was a strong trend for decreases in acute infections after NPWT. Thus, the authors opined that NPWT should be considered for high-risk wounds after severe skeletal trauma.
- Jiang et al. (2021) conducted a meta-analysis to compare the effectiveness and safety of negative pressure wound therapy (NPWT) and non-NPWT for individuals with skin grafts. Ten randomized controlled trials with 488 individuals with split-thickness skin grafts who underwent NPWT or non-NPWT were included in the study. Compared with non-NPWT, the group that received NPWT reported an improved rate of graft take and decreased need for re-operation when NPWT was utilized; however, incidence of adverse events, including infection, was not significantly different from standard treatment. Thus, the authors concluded that NPWT was more effective than non-NPWT for the integration of skin grafts; however, the authors noted that additional research aimed at understanding the complications after NPWT and the ideal negative pressure for the integration of skin grafts was imperative.
- A 2023 meta-analysis performed by Zhang and colleagues evaluated the effects of negative pressure wound therapy (NPWT) compared with conventional dressing on closed incisions in orthopedic trauma surgery. Fourteen studies and 3,935 individuals were included in the analysis. NPWT had significantly lower deep surgical site infections (SSIs) and wound dehiscence compared with conventional dressing. The investigators concluded that NPWT had a beneficial effect on deep SSIs, superficial SSIs, and wound dehiscence compared with conventional dressings in individuals with closed incisions in orthopedic trauma surgery. However, the authors noted that additional studies were needed to validate these findings.

- A 2022 systematic review conducted by Marouf and colleagues evaluated the efficacy of the immediate application of negative pressure wound therapy (NPWT) to the head and neck in free flap reconstruction. The study included four retrospective studies and five case-series that examined the immediate application of NPWT to the head and neck in free flap reconstruction. The most common reported indication for flap reconstruction was malignancy. The authors found that NPWT was applied to 56 free flaps and 54 had successful outcomes. Thus, the authors opined that NPWT had the potential to be a valuable tool for complicated wounds; however, further studies were needed to quantify functional and aesthetic outcomes.
- Lambrechts et al. (2002) conducted a systematic review and meta-analysis to determine if closed incision negative pressure wound therapy (ciNPWT) decreases surgical site infection (SSI) or wound dehiscence after spinal fusion. Eight studies comprising 1,061 patients who received ciNPWT or a standard postoperative dressing (control) after spinal fusion were included. The rate of SSI was significantly lower for patients treated with ciNPWT compared to the control group. In addition, there was not a significant difference between patients who received ciNPWT or a standard postoperative dressing with respect to requiring re-operations for wound debridement. Moreover, wound dehiscence was not significantly different between the two groups. Thus, the authors concluded that ciNPWT may reduce the rates of SSI after spinal fusion. The authors also noted that the use of ciNPWT may also significantly reduce the burden associated with postoperative wound complications; however, the meta-analysis was insufficiently powered to make this association, and thus, additional studies were warranted to further examine these conclusions.
- In a Cochrane review and meta-analysis, Norman et al. (2020) assessed the effects of negative pressure wound therapy (NPWT) for preventing surgical site infection (SSI) in wounds healing through primary closure. The study included 31 trials that reported SSI and compared NPWT with standard dressings. The authors reported moderate-certainty evidence that NPWT probably results in fewer SSI than treatment with standard dressings after surgery (8.8% compared with 13.0% of participants). The authors noted that most included studies had an unclear or high risk of bias for at least one key domain present in the studies.
- Guo et al. (2022) conducted a systematic review to evaluate the efficacy of negative pressure wound therapy (NPWT) for preventing surgical site infection (SSI) and other wound complications in obese women undergoing cesarean section. Ten randomized trials including 5,586 individuals were included in the study. The primary outcome was SSI. Secondary outcomes were seroma, hematoma, overall wound complications, and adverse skin reactions. The authors found that the use of prophylactic NPWT after cesarean delivery among obese women was associated with a significant reduction of surgical site infection. Moreover, it was noted that NPWT significantly increased the occurrence of skin blistering but no statistically significant difference was detected in the incidence of overall wound complications.

- In a meta-analysis, Svensson-Björket al. (2019) assessed the effects of incisional negative pressure wound therapy (NPWT) on the incidence of surgical site infection (SSI) in closed groin incisions after arterial surgery. The study included seven randomized controlled trials including 1,049 incisions. Meta-analysis demonstrated a reduction in SSI with incisional NPWT. Thus, the authors opined that NPWT applied to closed groin wounds after arterial surgery (open/endovascular aortic repair, lower extremity bypass) significantly reduced the risk of SSI. However, due to risk of bias present in the studies, the authors noted that additional high-quality randomized trials were warranted.
- A 2023 randomized trial conducted by Singh and colleagues examined the efficacy of negative pressure wound therapy (NPWT) in the management of incisional laparotomy subcutaneous wounds in gastrointestinal perforations. Sixty-nine patients were randomized to fascial closure and NPWT versus fascial closure and standard wound care. In both groups, delayed wound closure was attempted on postoperative day four. NPWT significantly reduced the incidence of surgical site infection (SSI) (17.6% versus 61.3%) and fascial dehiscence (9% versus 48%). Prophylactic NPWT also increased the rate of delayed primary wound closure (91% versus 48%) and decreased the median time to wound healing (19 days versus 26 days). The authors concluded that, in the absence of contraindications, NPWT can be used to expedite closure of contaminated surgical wounds. Moreover, the authors opined that prophylactic NPWT may also be useful for contaminated surgical wounds.

**Management of chronic wounds:**

- In 2022, a systematic review and meta-analysis (Shehata et al.) assessed the effectiveness of negative pressure wound therapy (NPWT) compared with conventional treatment in the management of different wound types, including acute and chronic wounds. Twenty-four studies including 3,064 patients were included in the meta-analysis. NPWT was associated with a shorter time to healing, shorter duration of treatment, and higher rate of wound healing compared with control. NPWT was also associated with a lower incidence of adverse events and a lower 30-day mortality rate. There were no significant differences between NPWT and control regarding hospital stay. In conclusion, the authors opined that NPWT was seemingly associated with better wound healing outcomes compared with conventional therapy. However, the authors noted multiple limitations to the analysis such as high heterogeneity between studies and small sample sizes of the included studies.
- A Cochrane review (Dumville et al., 2015) assessed the efficacy of negative pressure wound therapy (NPWT) for treating leg ulcers in any care setting. At the time of the meta-analysis, the authors found only one randomized controlled trial that was eligible for this review (Vuerstaek et al., 2006). The study population had a range of recalcitrant ulcer types that were venous arteriolosclerotic and venous/arterial in origin, and had not healed after treatment over a six-month period. Participants allocated to NPWT arm received continuous negative pressure until they achieved

100% granulation. A punch skin-graft transplantation was conducted, and the wound then exposed to further NPWT for four days, followed by standard care. Participants allocated to the control arm received standard care with dressings and compression until 100% granulation. The investigators reported low quality evidence of a difference in time to healing that favored the NPWT group. There was no evidence of a difference in the total number of ulcers healed (29/30 in each group) over the follow-up period. There was low quality evidence of a difference in time to wound preparation for surgery that favored NPWT. In conclusion, the investigators opined that there is limited evidence regarding the use of NPWT for the treatment of leg ulcers, with only one small trial reviewed that compared the use of NPWT with standard care before and after skin grafting; moreover, further research including large randomized controlled trials was warranted.

- A Cochrane review (Liu et al., 2018) assessed the effectiveness of negative pressure wound therapy (NPWT) compared with standard care or other therapies in the treatment of foot wounds in people with diabetes mellitus (DM). Eleven randomized controlled trials (972 participants) met the inclusion criteria. Two studies focused on post amputation wounds, and all other studies included foot ulcers in people with DM. Of note, ten studies compared NPWT with dressings. The primary outcome measures were the number of wounds healed and time to wound healing. The authors reported low-certainty evidence to suggest that NPWT, when compared with wound dressings, may increase the proportion of wounds healed, and reduce the time to healing for postoperative foot wounds and ulcers of the foot in people with DM. However, the authors noted that additional trials were needed given the limitations in the current evidence.
- Armstrong et al. (2005) reported on a randomized controlled trial which investigated whether negative pressure wound therapy (NPWT) improved the proportion and rate of wound healing in diabetic individuals after partial foot amputation. One hundred sixty two participants were randomized to a NPWT group with dressing changes every 48 hours (n=77) or a control group who received standard moist wound care (n=85). The results of the study demonstrated that more participants healed in the NPWT group (56%) than in the control group (39%). The rate of wound healing and rate of granulation tissue formation was faster in the NPWT group than in the control group. Moreover, the frequency and severity of adverse events were similar in both treatment groups. In conclusion, the authors found that compared with the control group, the NPWT group had a significantly higher percentage of individuals with healed wounds and shorter time to complete closure. Thus, the authors opined that NPWT was likely a safe and effective treatment for complex diabetic foot wounds.
- A multicenter, randomized controlled trial (Blume et al., 2008) evaluated the safety and clinical efficacy of negative pressure wound therapy (NPWT) compared with advanced moist wound therapy (AMWT) to treat foot ulcers in diabetic individuals. Three hundred forty-two participants were randomly assigned to either NPWT (vacuum-assisted closure) or AMWT (predominately hydrogels and alginates), and

received standard off-loading therapy as needed. The trial evaluated treatment until day 112 or ulcer closure by any means. Participants whose wounds achieved ulcer closure were followed at three and nine months. The study demonstrated that a greater proportion of foot ulcers achieved complete ulcer closure with NPWT (43.2%) than with AMWT (28.9%) within the 112-day active treatment phase. The participants who received NPWT experienced significantly fewer secondary amputations. In assessing safety, no significant difference between the groups was observed in treatment-related complications such as infection, cellulitis, and osteomyelitis at six months. In summary, the investigators concluded that accelerated wound healing with NPWT significantly reduced the time to wound closure in individuals with diabetes, returning these individuals to baseline more quickly and improving quality of life.

**Professional Organizations/Societies:**

- A 2023 Update of the International Working Group on the Diabetic Foot (IWGDF) evidence based guideline on wound healing interventions to promote healing of foot ulcers in persons with diabetes by Chen and colleagues made recommendations for the use of interventions to improve healing of foot ulcers in people with diabetes. The authors reported moderate desirable effects that negative pressure wound therapy (NPWT) may reduce the time to healing in postsurgical wounds, but not in chronic wounds when provided in addition to standard of care. Overall, the authors noted that the evidence behind the use of NPWT to improve the healing of diabetic ulcers was of low certainty; however, the authors noted that NPWT was generally considered acceptable to most patients and clinicians.
- A consensus-based practice guideline (Willy et al., 2017) noted that closed incision negative pressure therapy (ciNPT) may offer surgeons an additional option to manage clean, closed surgical incisions. The investigators conducted a literature search including 100 peer-reviewed studies published from 2000 to 2015. Numerous publications reported surgical site infection risk factors, with the most common including obesity, diabetes mellitus, tobacco use, or prolonged surgical time. The consensus panel recommended the use of prophylactic ciNPT on closed surgical incisions when there is a high number of individual-related and incision- or operation-related risk factors.
- The 2018 World Health Organization Global guidelines for the Prevention of Surgical Site Infection (SSI) evaluated whether the use of prophylactic negative pressure wound therapy (pNPWT) is more effective in reducing the risk of SSI than the use of conventional wound dressings without negative pressure therapy. The primary outcome was the occurrence of SSI and SSI-attributable mortality. Nineteen articles describing 21 studies that compared the use of pNPWT with conventional wound dressings were included in the analysis. The authors reported low quality evidence that pNPWT has a benefit in reducing the risk of SSI in patients with a primarily closed surgical incision following high-risk wounds when compared to conventional postoperative wound dressings.

- An evidence-based practice guideline (Vig et al., 2011) examined the use of negative pressure wound therapy (NPWT) for the treatment of chronic wounds. Thirteen evidence-based recommendations were created to address treatment goals, including: achieving wound closure, reducing wound dimensions, and improving the quality of the wound bed. The authors reported the strongest evidence for the use of NPWT in non-ischemic diabetic foot ulcers. In addition, the authors reported weaker evidence for the use of NPWT to treat chronic limb ischemia when all other modalities have failed or for the purpose of advanced wound care after revascularization, but NPWT was not indicated in acute limb ischemia.
- A 2020 Wound, Ostomy, and Continence Nurses (WOCN) Society guideline for the Management of Wounds in Patients with Lower-Extremity Venous Disease (LEVD) (Kelechi et al.) mentioned use of negative pressure wound therapy (NPWT) as an adjunct to compression therapy for the treatment of venous ulcers, although the authors reported a low level of evidence due to limited data to support the efficacy of this intervention.
- A Society for Vascular Surgery, American Podiatric Medical Association, and Society for Vascular Medicine clinical practice guideline (Hingorani et al., 2016) recommended negative pressure wound therapy (NPWT) for the treatment of diabetic foot ulcers that fail to demonstrate greater than 50% wound area reduction after four weeks of standard wound therapy. Moreover, the authors recommended NPWT for chronic diabetic foot wounds that do not improve after four to eight weeks of treatment with dressings.

## Codes addressed in this guideline

| HCPCS Code | Description                                                                                                |
|------------|------------------------------------------------------------------------------------------------------------|
| A6550      | Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories |
| A7000      | Canister, disposable, used with suction pump, each                                                         |
| E2402      | Negative pressure wound therapy electrical pump, stationary or portable                                    |

## References

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