Negative Pressure Wound Therapy

Policy Number: 2026T0594O
Effective Date: June 1, 2026

➲ Instructions for Use

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Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Notes:

- The proven and medically necessary coverage statements in this policy apply to the use of negative pressure wound therapy (NPWT) in the outpatient setting.
- The unproven and not medically necessary coverage statements in this policy apply to all settings.

NPWT, in an outpatient setting or on discharge from an inpatient setting, is proven and medically necessary for treating individuals who have undergone a complete wound therapy program and meet indication-specific criteria, as noted below.

A complete wound therapy program, meeting the following criteria, must have been tried or considered and ruled out prior to initiation of NPWT:

- Documentation of evaluation, care, and wound measurements; and
- Application of dressings to maintain a moist wound environment; and
- Debridement of necrotic tissue, if present; and
- Evaluation of and provision for adequate nutritional status; and
- Documentation, by provider, of the indication for NPWT; and
- Documentation that the open wound has not responded to conventional treatment after 30 days

Indications

- Pressure ulcer (stage III or IV), with documentation of the following:
  - Complete wound therapy program, as outlined above; and
  - Appropriate turning and positioning; and

    - Use of a pressure-reducing support surface; and
    - Moisture and incontinence management
- Neuropathic ulcer (e.g., diabetic ulcer), with documentation of the following:
    - Complete wound therapy program, as outlined above; and
    - Comprehensive diabetic management program; and
    - Reduction in pressure on the ulcer
- Venous insufficiency ulcer, with documentation of the following:
    - Complete wound therapy program, as outlined above; and
    - Compression bandages and/or garments have been used consistently for at least 30 days; and
    - Leg elevation and ambulation
- Open surgical wound, with documentation of the following:
    - Postoperative dehiscence (separation of a previously closed surgical incision), with documentation of a complete wound therapy program, as outlined above; or
    - Open, nonhealing amputation site in individuals with diabetes; or
    - Poststernotomy infection (mediastinitis); or
    - Delayed healing or nonhealing of a skin graft is likely due to irregularly contoured or inadequate blood flow of the graft bed
- High-risk open fracture (Gustilo Grade III)

The following indications and devices are unproven and not medically necessary due to insufficient evidence of efficacy:

- NPWT for treating **all** other indications, including but not limited to:
    - Closed surgical incisions
    - Pilonidal disease
- Disposable/single-use NPWT systems
- NPWT systems with instillation of wound solutions

Contraindications to NPWT

- Active bleeding or exposed vasculature in the wound
- Anticoagulation therapy
- Eschar or necrotic tissue present in the wound
- Exposed bone, nerves, or organs in the vicinity of the wound
- Malignancy present in the wound
- Uncontrolled soft tissue infection or untreated osteomyelitis in the vicinity of the wound
- Presence of an open fistula to body organs or cavities in the vicinity of the wound

NPWT should be discontinued when **any** of the following criteria are present:

- Documentation of weekly assessment of the wound's dimensions and characteristics by the provider indicates failure of progressive wound healing [i.e., wound is not diminishing in size (either surface area or depth) within 30 days]; or
- The depth of the wound is 1 mm or less; or
- Uniform granulation tissue has been obtained

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

Gustilo Grade III Fracture: An open fracture with extensive soft tissue damage or an open segmental fracture.

- IIIA: Adequate soft tissue coverage of a fractured bone despite extensive soft tissue laceration or flaps or high-energy trauma regardless of wound size.
- IIIB: Extensive soft tissue injury loss with periosteal stripping and bone exposure; associated with massive contamination and often requires soft tissue coverage (e.g., flap).
- IIIC: Arterial injury requiring repair.

(Gustilo and Anderson, 1976; Gustilo et al., 1984)

National Pressure Injury Advisory Panel Staging System (NPIAP, 2019):

- Stage III: Characterized by full-thickness loss of skin in which 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, then this is an unstageable pressure injury.
- Stage IV: Characterized by 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, then this is an unstageable pressure injury.
- Unstageable pressure injury: Characterized by obscured, 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 III or stage IV pressure injury will be revealed. Stable eschar (i.e., dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

Coding Clarification: Suction pumps and dressing codes (HCPCS codes K0743-K0746) apply to devices other than negative pressure wound therapy.

CPT 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	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	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

HCPCS Code	Description
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

Description of Services

Negative pressure wound therapy (NPWT), also referred to as vacuum-assisted wound closure, is a therapeutic dressing system in which negative pressure is continuously or intermittently applied to the surface of a wound. The system includes dressings, a suction pump, tubing, and a collection chamber. The wound and porous dressing are sealed with an occlusive dressing and connected to the drainage tubing connected to a suction pump that delivers subatmospheric pressure. NPWT is intended to assist wound healing by the removal of exudate or debris, reduction of bacterial contamination, increase in local blood flow, reduction of local edema, approximation of the wound edges, and production

of granulation tissue. NPWT is intended as an adjunct treatment for wounds that do not respond to conventional treatment such as debridement, pressure relief, and infection control.

Clinical Evidence

Despite a lack of strong evidence to support its use, negative pressure wound therapy (NPWT) has gained wide acceptance for a variety of wounds.

Hurd et al. (2021) published consensus-based recommendations on the use of NPWT in acute and chronic wound management. The document presents a clinical decision-making tool for initiating NPWT and the optimal system to be used based on a number of factors.

Kirsner et al. (2019) conducted a multicenter, randomized, comparative efficacy study in participants with venous leg ulcers or diabetic foot ulcers. The study compared the change in target ulcer dimensions (area, depth, and volume) using single-use NPWT (s-NPWT) vs traditional NPWT (t-NPWT) over a 12-week treatment period or up to confirmed healing. Randomized by wound type and size, 164 participants with noninfected diabetic foot ulcers and venous leg ulcers were included. The intention-to-treat (ITT) population comprised 161 participants (101 with venous leg ulcers, 60 with diabetic foot ulcers), and 115 participants completed follow-up (64 in the s-NPWT group and 51 in the t-NPWT group; per-protocol population). Primary end point analyses on wound area reduction demonstrated a statistically significant reduction in favor of s-NPWT ($p = 0.003$) in the per-protocol population and in the ITT population ($p < 0.001$). Changes in wound depth ($p = 0.018$) and volume ($p = 0.013$) were also better with s-NPWT. Faster wound closure was observed in the ITT population. Wound closure occurred in 45% of participants in the s-NPWT group vs 22.2% of participants in the t-NPWT group ($p = 0.002$). The median estimate of the time to wound closure was 77 days for s-NPWT. No estimate could be provided for t-NPWT. Device-related adverse events were more frequent in the t-NPWT group than in the s-NPWT group. The s-NPWT system met noninferiority and achieved statistical superiority vs t-NPWT in terms of wound progression toward healing over the treatment period. This study was limited by small numbers and short-term follow-up. Also, the study was designed to compare two types of NPWT systems, not to compare NPWT against standard of care or standard dressings.

Pressure Ulcers

An updated Cochrane systematic review that was first published in 2015 (updated 2023) evaluated the effectiveness of NPWT for treating adults with pressure ulcers in any care setting. Eight randomized controlled trials (RCTs) were included, with a total of 327 individuals. Five studies compared NPWT with dressings. The evidence for this outcome was assessed as very low certainty [risk ratio (RR), 1.25; 95% CI, 0.64-2.44]. One study compared NPWT with a series of gel treatments, but this study provided no usable data. Another study compared NPWT with moist wound healing and did not report primary outcome data. The last study compared NPWT combined with internet-plus home care with standard care, and no primary outcome data were reported. All studies demonstrated a low certainty of evidence. The authors concluded that the efficacy, safety, and acceptability of NPWT in treating pressure ulcers compared with those of usual care are uncertain due to the lack of key data on complete wound healing, adverse events, and time to complete healing. Further high-quality research is still needed to help decision-makers judge the value of NPWT in the treatment of pressure ulcers. Limitations of the study evidence include small sample sizes, poorly reported or unclear duration, limited data, and inconclusive adverse effects (Shi et al., 2023).

Sahin et al. (2021) conducted an RCT on the effectiveness of NPWT compared with that of wet-to-dry dressing in pressure injuries. Overall, 30 participants with stage 3 and 4 pressure injuries were divided into two groups: the NPWT group and the wet-to-dry-dressing group. Following three rounds of treatment in all participants, data were collected using a three-dimensional wound measurement device, the Pressure Ulcer Scale for Healing (PUSH) tool, and a participant identification form. The data revealed significant granulation tissue formation in the experimental group ($p < 0.05$), with significant wound shrinkage ($p < 0.05$) and a decrease in PUSH tool scores ($p < 0.05$). Participants' wounds were assessed with the PUSH tool and three-dimensional wound measurement system, which showed that device measurements were correlated with PUSH tool findings ($p < 0.05$), with a significant correlation noted between device-measured granulation findings and PUSH tool score results for the experimental group's third measurements ($p < 0.05$). The authors concluded that NPWT is an effective treatment measure for pressure injuries. Limitations include the small sample size and short-term follow-up. The authors recommended future studies that include larger sample sizes and monitor treatment efficacy until the wound has completely healed.

Neuropathic Ulcers

Gu et al. (2025) conducted a multicenter prospective RCT to evaluate the comparative efficacy of NPWT and advanced moist wound therapy (AMWT) in treating diabetic foot ulcers. The study included 450 adult participants (mean age, 60 $\pm$10 years; 78% male) who had confirmed diabetic foot ulcers (91% with type 2 diabetes; 9% with type 1 diabetes) meeting

Wagner grade 1 to 3 classification criteria, with a postdebridement ulcer area of at least 2 cm^2 and adequate peripheral circulation. Participants were randomized to receive either NPWT (n = 204) or AMWT (n = 246) over 18 months. The NPWT group was treated with a vacuum-assisted closure (VAC) system, evacuation pad, and polyurethane or polyvinyl alcohol foam dressing. Negative pressure settings ranged from -50 to -200 mm Hg, based on wound characteristics, with dressing changes every 48 to 72 hours and continued until complete wound closure, satisfactory granulation tissue formation, or up to day 112 (whichever occurred first). The AMWT group received advanced dressings (such as hydrogels and alginates), with dressing changes every 24 to 48 hours. Both groups received adjunctive wound care, including surgical debridement and off-loading as needed. The primary outcome was complete ulcer closure, while the secondary outcomes were time to closure, wound size reduction, infection rates, recurrence, and amputation rates. The authors reported that there was a statistically significant difference in clinical outcomes, with complete ulcer closure achieved in 177 participants (87%) in the NPWT group and 72 participants (29%) in the AMWT group achieving complete ulcer closure ($p < 0.001$). However, the mean time to wound closure was reported by the authors to be marginally extended in the NPWT group (73 $\pm$45 days) compared with the AMWT group (64 ±49 days) ($p < 0.001$). The authors also reported that analyses of secondary outcomes showed that NPWT was associated with markedly reduced adverse events, including wound infection [40 participants in the NPWT group (20%) vs 95 participants in the AMWT group (39%); $p < 0.001$], ulcer recurrence [40 participants (20%) vs 113 participants (46%); $p < 0.001$], and amputation rates [30 participants (15%) vs 132 participants (54%); $p < 0.001$]. Noted limitations include the lack of blinding and the exclusion of participants with uncontrolled diabetes and significant comorbidities, which limit the study's generalizability. The authors concluded that the study demonstrates that NPWT was significantly more effective than AMWT in managing diabetic foot ulcers, as NPWT led to superior outcomes in ulcer closure, complication reduction, and lower amputation rates.

Wu et al. (2023) conducted an RCT to compare the efficacy of NPWT and alginate dressings on wound bed preparation prior to split-thickness skin graft (STSG) surgery in participants with chronic diabetic foot ulcers. Participants were randomly assigned to two groups: NPWT (with VAC, n = 50) or the control group (with alginate dressings, n = 50). The results demonstrated that the participants in the NPWT group had less time to STSG surgery than the control group. The participants in the NPWT group had prominently increased survival rates of skin graft, increased wound blood perfusion, decreased neutrophil extracellular trap formation, and polarization of macrophages. The authors concluded that NPWT is superior to conventional moist dressings in wound preparation prior to STSG surgery in individuals with chronic diabetic foot ulcers. A limitation of this study is that it was not a multicenter trial; additionally, the sample size was small, and no long-term follow-up was conducted.

A systematic review and meta-analysis performed by Wang et al. (2022) compared the efficacy and safety of NPWT with those of moist wound care (MWC) in the treatment of diabetic foot ulcers. Overall, 10 RCTs (619 individuals in the NPWT group and 625 in the MWC group) were included in the review, and eight trials were included for qualitative and quantitative syntheses. The clinical outcomes analyzed healing results, amputation or resection incidence, and risk of adverse events. The data demonstrated a significantly lower risk of nonclosure of the wound (RR, 0.74; 95% CI, 0.63-0.87; $p = 0.001$), lower average wound area (standard mean difference, -0.80; 95% CI, -1.54 to -0.06; $p = 0.034$), more wound area decrease (standard mean difference, 0.81; 95% CI, 0.36-1.26; $p = 0.001$), an increase in the appearance rate of granulation tissue (RR, 1.61; 95% CI, 1.07-2.41; p-0.021), and a lower risk of amputation or resection (RR, 0.70; 95% CI, 0.50-0.99; $p = 0.045$) in the NPWT group than the MWC group. There was no statistically significant distinction found for the disappearance rate of wound discharge at 8 weeks, the rate of blood culture positivity, pain scoring, and the overall prevalence of adverse events between the groups ($p = 0.05$). The authors concluded that NPWT could accelerate the wound healing process and decrease the risk of posttreatment amputation or resection, without any additional frequency of adverse events compared with MWC, in individuals with diabetic foot ulcers. Limitations include the addition of RCTs, which had relatively low quality and small sample sizes, to the study. The authors recommended that more high-quality RCTs are needed to identify the treatment efficacy of NPWT compared with that of MWC.

A Hayes report on the use of NPWT in the home setting as an adjunct treatment for chronic wounds in adults reported on three studies for chronic diabetic foot ulcers. The studies found benefit with NPWT for complete wound healing or wound closure. An additional study found that the time to wound closure was shorter in individuals receiving NPWT (Hayes, 2016; updated 2021).

Rys et al. (2020) conducted a systematic review and meta-analysis of 16 observational studies (n = 1,882 managed with NPWT) and evaluated the efficacy and safety of NPWT in individuals with diabetic foot ulcers. In the NPWT-treated individuals, ulcers were larger (average size range, 6.6-27.9 cm^2) than those in controls (≤ 3 cm^2). The pooled results showed healing and major amputation in 51% and 5% of NPWT individuals, respectively. A meta-analysis of four comparative studies revealed a lower risk of major amputation in NPWT-treated individuals. The pooled results for healing rate and risk of any amputation were inconclusive due to the large heterogeneity between the studies. These results support earlier RCT data that showed that NPWT is an effective and safe adjunct therapy in the management of diabetic foot ulcers.

An updated Cochrane systematic review assessed the effects of NPWT compared with those of standard care or other adjuvant therapies in the healing of diabetic foot wounds. Overall, 11 RCTs (n = 972) were included. The authors found low-certainty evidence to suggest that NPWT may be effective in healing postoperative foot wounds and ulcers of the foot in people with diabetes compared with wound dressing in terms of the proportion of wound healed and time to healing. For the comparisons of different pressures of NPWT for treating foot ulcers in people with diabetes, it is uncertain whether there is a difference in the number of wounds closed or covered with surgery and adverse events. None of the included studies provided evidence on time to closure or coverage surgery or health-related quality of life (Liu et al., 2018).

Venous Insufficiency Ulcers

Ulloa et al. (2025) conducted a single-arm, single-center, open-label, prospective study (the SPACE study) to evaluate the clinical effectiveness and safety of NPWT in hard-to-heal venous leg ulcers as an adjunct to standard wound care. The study included 59 adults (median age, 66 years; 69% female; all Hispanic or Latino) with venous leg ulcers that had not progressed by at least 30% in the previous 4 weeks. The wounds were 1 to 3 months of age [15 (25%)], 3 to 6 months [21 (36%)], 6 to 9 months [10 (17%)], or 9 to 12 months [13 (22%)], while the location of the wounds was the ankle [22 (37%)], calf [19 (32%)], or gaiter [18 (31%)]; most were positioned medially [36 (61%)]. Each participant received NPWT with the Avelle NPWT system at the screening/baseline visit, with scheduled follow-up visits on day 6 ±1 and day 13 ±1. The primary end points were baseline change in wound size and dressing durability. In those treated per protocol (n = 50), the authors reported that the mean ± SD wound area was 13.4 ±17.0 cm^2 at baseline and 7.3 ±9.9 cm^2 at study completion (46.8% reduction; $p < 0.001$) and that the median dressing wear time was 6 days, with changes due to dressing saturation reported in three or fewer participants (6%). The authors also reported that 13% of the participants had signs of eczema/dermatitis, hyperkeratotic callus, maceration, or edema, and there were no signs of infection. One participant withdrew after experiencing device-related dermal lesions, and one participant had an unrelated serious adverse event. Limitations noted by the authors include the single-center design, lack of diversity in the study population, single-arm design, small wound sizes, inclusion of participants with multiple comorbidities, variability in the application of compression among participants, and short follow-up period. The authors concluded that the management of hard-to-heal venous leg ulcers with NPWT for 2 weeks was associated with a significant reduction in wound size, effective exudate control, and a good safety profile and recommended future studies that have longer treatment and follow-up time.

A Hayes report on the use of NPWT in the home setting as an adjunct treatment for chronic wounds in adults found one study demonstrating that venous ulcers were more likely to heal among individuals who received NPWT than among those who did not (Hayes, 2016; updated 2021).

Open Surgical Wounds

Polomska et al. (2025) conducted a systematic review to evaluate outcome measures of NPWT effectiveness and a meta-analysis to assess whether NPWT is effective in preventing surgical site infection in abdominal surgery. The systematic review included eight studies (three RCTs and five cohort studies), with 1,655 individuals who had undergone surgery for gastrointestinal perforation and/or emergency abdominal surgery. There were two studies that did not have a comparator arm and one study that used primary closure with NPWT application [closed-incision NPWT (ciNPWT)] that were not included in the meta-analysis. Seven of the eight studies included individuals with class III/IV wounds. Two studies had a significantly lower median age than the other studies and were conducted in middle-income countries, while the remaining studies were conducted in high-income countries. The included studies had two main control intervention types: delayed primary closure (DPC) and primary closure. There were 748 individuals who received NPWT with DPC, 374 who underwent primary closure, and 25 who underwent ciNPWT. The authors reported that in the meta-analysis of the three included studies that compared NPWT with primary closure (n = 509), NPWT resulted in better outcomes than primary closure for surgical site infection reduction; however, in the three studies that compared NPWT with DPC (n = 1,073), the surgical site infection risk difference between NPWT and DPC was not statistically significant. Overall, the studies were found to have a moderate risk of bias. Limitations include the high degree of heterogeneity between study designs and interventions in the included studies; differences in median age and socioeconomic statuses; and ambiguity in the descriptions of interventions and outcome measures. The authors also noted that a major limitation of the meta-analysis was the small number of studies and low total number of individuals included in the analyses. The authors concluded that preventive NPWT was associated with a reduced risk of surgical site infection in abdominal surgery compared with primary closure; however, the certainty of the evidence was low due to the heterogeneity of the studies and the risk of bias. The authors recommended large-scale RCTs that have optimized protocols regarding precisely described interventions and objective outcome reporting.

The Cochrane Library (Cheng et al., 2022) performed a systematic review that compared NPWT with any other type of temporary abdominal closure in nontrauma individuals with an open abdomen in any care setting. A secondary comparison was performed for different types of NPWT systems. Based on the available trial data, in which only two studies met the inclusion criteria, the authors concluded that there is uncertainty whether NPWT has any benefit in terms

of primary fascial closure of the abdomen, adverse events (fistulae formation), all-cause mortality, and length of hospital stay. Given this uncertainty of evidence in this review, clinicians, individuals, and other stakeholders may need to take into account other considerations when making treatment decisions.

A Hayes Evidence Report summarized the publications related to the use of NPWT in the outpatient setting for the treatment of chronic wounds. The report described the potential benefits of NPWT, which included symptom management, reduced frequency of dressing changes, and faster healing times. However, there may be potential harm associated with NPWT such as pain, retention of foreign bodies from the dressing, bleeding, infection, death from infection, and complications stemming from loss of electricity (Hayes, 2022).

Open Fractures

Alves et al. (2024) conducted a systematic review and meta-analysis to assess the effectiveness of NPWT compared with that of conventional wound dressing (CWD), also described as standard wound coverage without subatmospheric pressure, in the management of Gustilo III lower limb fractures, with a focus on overall rates, superficial infection, and deep infection rates. A systematic review of medical research databases was conducted in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Studies comparing NPWT with CWD for Gustilo III fractures were included. Data extraction and quality assessment were performed. Treatment with CWD was associated with higher rates of overall infection (RR, 0.33; 95% CI, 0.14-0.51) and pooled risk difference (risk difference, 0.27; 95% CI, 0.15-0.38), superficial infection (pooled RR, 0.35; 95% CI, 0.04-0.66), and deep infection (pooled RR, 0.20; 95% CI, 0.02-0.38) than NPWT treatment. The overall infection rate remained higher in the CWD group after analyzing only open tibia fractures (pooled RR, 0.35; 95% CI, 0.21-0.48). The nonunion rate was higher in the CWD group (pooled RR, 0.30; 95% CI, 0.00-0.59). The flap failure rate was similar in both groups (pooled RR, 0.09; 95% CI, -0.05 to 0.23). The authors concluded that NPWT appears to be a reasonable option for wound management in Gustilo III lower limb fractures in terms of infection rates. This systematic review and meta-analysis has limitations. First, there is a paucity of high-quality RCTs specifically addressing Gustilo III lower limb fractures. Second, treatment protocols varied across studies, and most did not provide full details of their wound care protocol. Additionally, details of bone fixation and soft tissue coverage were often limited and lacked specificity. The final reported outcomes were mainly based on subjective and nonquantifiable measures. These variations in study design and reporting standards highlight the complexity and heterogeneity of Gustilo III fractures. Furthermore, the present meta-analysis may not capture all the relevant clinical nuances and individual-specific factors influencing treatment decisions. The findings of this study need to be validated by well-designed studies.

Over a 5-year period, Costa et al. (2024) conducted the WHIST (Wound Healing in Surgery for Trauma) trial and reported the outcomes in participants with complex fracture of the lower limb. The trial compared NPWT dressings with standard dressings applied at the end of the first operation in participants undergoing internal fixation of the fracture. Complex fractures included periarticular fractures and open fractures when the wound could be closed primarily at the end of the first debridement. A total of 1,548 participants, who were aged 16 years or older, completed the initial follow-up 6 months after injury. Participants reported their Disability Rating Index (DRI), health-related quality of life, chronic pain scores, and neuropathic pain scores annually, along with any complications. The results demonstrated that there was no evidence of a difference in participant-reported disability between the two groups at 5 years (NPWT), with a group mean DRI of 30.0 (SD, 26.5), standard dressing group mean DRI of 31.5 (SD, 28.8), and adjusted difference of -0.86 (95% CI, -4.14 to 2.40; p = 0.609). Also, there was no difference in complication rates. The study had limited follow-up, during which only 66% of the 1,548 participants provided data during the 5 years; therefore, the study did not have the same statistical power to detect subtle differences in outcomes. The authors concluded that there was no evidence of a difference in disability ratings between NPWT compared with standard wound dressings in the 5 years following the surgical treatment of a complex fracture of the lower limb. Participants in both groups reported high levels of persistent disability and reduced quality of life.

Haidari et al. (2021) performed a systematic review to assess the role of NPWT in the management of soft tissue defects in individuals with fracture-related infection (FRI). Eight articles that focused on the infection recurrence, which ranged from 2.8% to 34.9%, were included in the review. Six studies reported on wound healing time, which varied from 1 to 7 weeks. Four studies took repeated microbial swabs during subsequent NPWT dressing changes. One study reported newly detected pathogens in 23% of the included individuals, and three studies did not find new pathogens. The authors concluded that there is no clear evidence to support the use of NPWT for FRI as definitive treatment. However, the authors did recommend early soft tissue coverage with a local or free flap, stating that NPWT may be safe for a few days as temporary soft tissue coverage until further definitive treatment can be performed. The authors noted that due to the lack of uniformity in the studies, caution should be used when drawing conclusions, and further comparative studies are needed. Limitations include the limited number of high-quality studies on FRI treatment with NPWT, lack of uniformity between the studies, and small sample sizes.

In the multicenter randomized WOLFF trial, 460 participants with a severe open fracture of the lower limb were treated with NPWT (n = 226) or standard dressings without NPWT (n = 234). At 12 months, deep surgical site infection rates, self-rated disability, and quality of life were similar in both groups (Costa et al., 2018).

In a Cochrane systematic review, Iheozor-Ejiofor et al. (2018) evaluated the effectiveness of NPWT for treating open traumatic wounds. Seven RCTs (n = 1,377) were included. Study sample sizes ranged from 40 to 586 individuals. Four studies compared NPWT with standard care for open fracture wounds. The authors concluded that there is moderate-certainty evidence for no clear difference between NPWT and standard care on the proportion of wounds healed at 6 weeks for open fracture wounds. It is uncertain whether there is a difference in risk of wound infection, adverse events, time to closure or coverage surgery, pain, or health-related quality of life between NPWT and standard care for any type of open traumatic wound.

Virani et al. (2016) conducted a prospective randomized trial to evaluate the role of NPWT in the incidence of deep infections/osteomyelitis after open tibial fractures. Overall, 93 adults with open tibial fractures were randomized into two groups: NPWT and daily cleaning, dressing, and debridement. After 23 weeks, the rate of infection was significantly lower (4.6%) in the NPWT group than the control group (22%). NPWT was also associated with less bacterial colonization (6.9% vs 34%) of wounds compared with the control group. Five participants (25%) from the control group developed osteomyelitis. The authors concluded that NPWT is beneficial for preventing the incidence of both acute infections and osteomyelitis in open fractures. The time required for the wounds to be ready for closure or coverage was similar in both groups (8.3 vs 9.8 days).

Tansarli et al. (2014) performed a meta-analysis of four RCTs (n = 367) that evaluated the incidence of surgical site infections in individuals with open wounds following fracture stabilization. Infection rates in individuals whose wounds were treated with VAC (n = 196) were reduced by 53% compared with nonvacuum closure (n = 171).

Closed Surgical Incisions

There is insufficient clinical evidence that demonstrates the safety and/or efficacy of NPWT systems, including disposable systems, for treating closed surgical incisions. Studies to date have been too small or at a risk of bias to support routine use. Further results from prospective, high-quality studies are needed to determine which population of individuals would benefit from the use of these devices.

In their systematic review, Feier et al. (2025) evaluated the use of ciNPWT for hepato-pancreato-biliary surgery to evaluate its effectiveness and safety. The systematic review included 12 studies (seven RCTs, four cohort studies, and one registry analysis), with 15,982 individuals (4,455 ciNPWT and 11,527 controls) and device applications of 3 to 7 days in the treatment groups. Seven of the studies addressed pancreatic resection, with the remainder evaluating liver transplant, mixed hepatectomy with or without pancreatectomy, broad laparotomy oncology cohorts, or national-level pancreatectomy data. The devices used were variable, with PICO™ having been used in five studies, Prevena™ in four studies, iVAC® in one study, and mixed dressings in the registry analysis. The authors reported that the pooled analysis showed a 29% relative reduction in superficial surgical site infections with the use of ciNPWT, with a weighted superficial surgical site infection rate of 9.1% vs 12.6% for standard dressings. The authors also reported that deep/organ space surgical site infection and 90-day mortality were unaffected and that device-related adverse events were exceedingly rare. In seven studies, the authors reported that they found a 1- to 3-day shorter median length of stay, although only two of these studies reached statistical difference. This systematic review was limited by the heterogeneity of the devices included in the studies; lack of ability to do meta-analyses for many secondary end points due to the use of nonstandard surgical site infection definitions in many of the studies; inconsistent follow-up intervals; and divergent composite outcomes. The lack of universally adopted outcome sets and variable device protocols were also limitations; additionally, two liver-specific RCTs and one high-volume pancreatic RCT were only available as conference abstracts. Finally, this systematic review was limited by the inclusion of the registry, which accounted for 92% of all individuals, and by the lack of follow-up beyond 30 days, which limited the identification of late outcomes (such as incisional hernia, chronic pain, and patient-reported quality of life). The authors concluded that prophylactic ciNPWT safely reduced superficial surgical site infection by approximately one-third and shortened the hospital stay following high-risk hepato-pancreato-biliary surgery. The Moreno et al. (2025) study, previously summarized in this policy, was included in this systematic review.

The SUNRRISE Clinical Trial Group et al. (2025) conducted a multicenter, assessor-masked, phase 3 RCT to evaluate the effectiveness of incisional NPWT (iNPWT) in reducing the rate of surgical site infection in participants undergoing emergency laparotomy with primary skin closure. The study included 840 participants (52% female; mean age, 63.8 years) who underwent emergency laparotomy in 22 hospitals in the UK and 12 hospitals in Australia; participants were followed up for 30 days post procedure. Study participants were randomized 1:1 to receive iNPWT (n = 411) or the surgeon's choice of wound dressing (n = 410) while in the operating room at the end of the surgical procedure. After postrandomization exclusions (n = 52), there were 394 participants in each study group who were included in the primary

analysis. The authors reported that 112 participants (28.4%) developed a surgical site infection in the iNPWT group compared with 108 participants (27.4%) in the surgeon's preference group and that this finding was consistent across the preplanned subgroup analyses, including degree of contamination, presence of a stoma, participant body mass index, and skin preparation used. The authors also reported that six of seven secondary outcomes (including hospital readmission, quality of life, wound complications, and hospital length of stay) showed no significant differences. This study was limited by the lack of blinding of the care team, lack of specificity for the type of surgical site infection, inclusion of only one iNPWT product, lack of inclusion of children, and exclusion of participants unlikely to survive 30 days after the procedure. The authors concluded that this study does not support the routine application of iNPWT to closed surgical wounds after emergency laparotomy for the reduction of surgical site infection in adults undergoing emergency laparotomy.

Mantyh et al. (2024) conducted a systematic review and meta-analysis to assess the impact of closed-incision negative pressure therapy (ciNPWT) on postsurgical outcomes in individuals undergoing open abdominal surgeries. The literature search identified 22 studies from nine countries that met the inclusion criteria. The results showed that significant reductions in the relative risk of surgical site complications (relative risk, 0.568; $p = 0.003$), surgical site infection (relative risk, 0.512; $p < 0.001$), superficial surgical site infection (relative risk, 0.373; $p < 0.001$), deep surgical site infection (relative risk, 0.368; $p = 0.033$), and dehiscence (relative risk, 0.581; $p = 0.042$) were associated with ciNPWT use. ciNPWT use was also associated with a reduced risk of readmission and a 2.6-day reduction in hospital length of stay ($p < 0.001$). The authors concluded that ciNPWT was associated with an overall reduction in surgical site complications, hospital length of stay, and readmissions. Although the findings of this meta-analysis indicate that ciNPWT is beneficial and could potentially result in cost savings for individuals undergoing abdominal surgery, additional research is needed to determine the optimal use of ciNPWT in this population and provide a robust assessment of the cost-effectiveness of the therapy. Limitations of the study include study design, potential for selection bias, varied ciNPWT training, and differences in outcome measures reporting.

In an ECRI Clinical Evidence Assessment on NPWT for preventing surgical site infection after cesarean section in women with obesity, it was concluded that based on evidence reported in two systematic reviews with meta-analyses, NPWT is safe and reduces surgical site infections compared with conventional dressings. One reported lower rates of dehiscence, seroma, hematoma, and bleeding, and the other showed similar complication rates when NPWT was compared with conventional dressings when all wound complications were grouped. One systematic review reported similar rates of reoperation and readmission (2024).

Hayes published a Health Technology Assessment on the use of NPWT for closed surgical incisions following hip arthroplasty, which concluded that there is insufficient published evidence to assess the safety and/or impact on health outcomes or individuals' management for the use of NPWT in these surgical cases compared with those of conventional surgical wound care. The assessment included a review of six clinical studies that met the inclusion criteria (four RCTs and two retrospective studies), which were found to be, overall, a very low-quality body of evidence. No new studies were identified in their 2025 assessment that met the inclusion criteria. The report stated that the studies showed that NPWT did not provide consistent benefits and that most benefits had limited clinical importance. The report concluded that additional RCTs are needed to evaluate the effectiveness and safety of NPWT, particularly in individuals with an elevated risk of wound complications due to comorbidities (2023; updated 2025).

Another Hayes Health Technology Assessment (2023; updated 2025) was conducted on the use of NPWT for closed surgical incisions following total knee arthroplasty (TKA). Initially, Hayes evaluated seven relevant clinical studies that met their inclusion criteria, consisting of three RCTs, one prospective comparative trial, one retrospective comparative trial, and one retrospective trial with historical controls. Hayes concluded that there is an overall low-quality body of evidence that suggests that NPWT is reasonably safe but provides limited or inconsistent benefit for the management of closed surgical incisions after TKA. In their 2025 update, two additional studies were identified that may meet their inclusion criteria; however, no change was made to their position based on a review of the abstracts. Hayes stated that additional RCTs are needed to evaluate the safety and efficacy of NPWT, particularly in individuals with an elevated risk of wound complications following TKA due to comorbidities.

A Hayes Evolving Evidence Review found minimal support for the use of PICO s-NPWT systems for wound care in women with clinical obesity following a cesarean birth. A limited amount of clinical evidence and one clinical practice guideline indicate some support for the use of s-NPWT in this population; however, study conclusions were inconsistent. In the 2025 update, Hayes identified four newly published clinical studies and nine newly published systematic reviews that may meet their inclusion criteria. Based on a review of the abstracts of these studies, two key abstracts were identified. Hayes stated that it is possible that a full review of these studies may result in an upgrade to their minimal level of support for the use of NPWT for wound care in this clinical scenario and that it is not likely to change their current minimal level of support for systematic reviews or their weak support designation for clinical practice guidelines (Hayes, 2021a; updated 2025).

A Hayes report on the prophylactic use of NPWT following elective open abdominal surgeries concluded that the current body of overall low-quality evidence suggests that there may be a benefit with NPWT over standard sterile dressing that is driven by a lower rate of superficial infections; however, recent RCT evidence has not confirmed these findings, and uncertainty remains. Significant heterogeneity exists between the populations of individuals, underlying reason for abdominal surgery, and treatment characteristics in the included body of evidence, making it difficult to discern which individuals might benefit most from this form of prophylaxis (Hayes, 2021b; updated 2024).

An updated Cochrane review (Norman et al., 2020) assessed the effects of NPWT for preventing surgical site infection in wounds healing through primary closure. This update added 15 new RCTs, resulting in a total of 44 RCTs (n = 7,447). Studies evaluated NPWT in the context of a wide range of surgeries, including orthopedic, obstetric, vascular, and general procedures. Most studies had an unclear or high risk of bias for at least one key domain. The review concluded that there was no clear difference in the number of deaths or wound dehiscence between people treated with NPWT and standard dressings (low-certainty evidence). There were also no clear differences in secondary outcomes, for which all evidence was low or very low certainty. In cesarean section in obese women and surgery for lower limb fracture, there was probably little difference in quality-of-life scores (moderate-certainty evidence). Most evidence on pain was very low certainty, but there was probably no difference in pain between NPWT and standard dressings after surgery for lower limb fracture (moderate-certainty evidence). A fourth update of this review (Norman et al., 2022) added 18 new RCTs to the study, for a total of 62 RCTs that included 13,340 individuals. Once more, the studies evaluated a wide range of surgeries, including orthopedic, obstetric, vascular, and general procedures. All studies compared NPWT with standard dressings. Most studies had an unclear or high risk of bias for at least one key domain. The results concluded that there was no difference in wound dehiscence (moderate-certainty evidence) among people with primary closure of their surgical wound that was treated prophylactically with NPWT following surgery compared with people treated with standard dressings; however, NPWT probably results in fewer surgical site infections than standard dressings. There may be a reduced risk of death after surgery in those who are treated with NPWT compared with standard dressings (low-certainty evidence). Also, there may be more instances of skin blistering when comparing NPWT with standard dressing treatment (low-certainty evidence). There is no clear difference in secondary outcomes, for which most evidence is low or very low certainty. Decisions about NPWT use should consider surgical indication, setting, and evidence for all outcomes.

Two separate RCTs (Tuuli et al., 2020; Hussamy et al., 2019) found that prophylactic NPWT did not significantly reduce the risk of postoperative wound morbidity compared with standard wound dressing in obese women undergoing cesarean delivery. The Tuuli et al. study (included in the 2022 Cochrane review above) was terminated after 1,624 of 2,850 participants were recruited when a planned interim analysis showed increased adverse events in the NPWT group and futility for the primary outcome of reduced surgical site infections.

In the WHIST multicenter RCT, Costa et al. (2020) assessed outcomes of iNPWT (n = 785) vs those of standard wound dressing (n = 763) on deep surgical site infection after surgery for lower limb fractures associated with major trauma. At 30 days, deep surgical site infection occurred in 5.84% (45 of 770 participants) of the iNPWT group and in 6.68% (50 of 749 participants) of the standard wound dressing group. At 90 days, there was no significant difference in the infection rates between groups. Additionally, there were no significant differences, at any time point, for the secondary outcomes of participant-reported disability, health-related quality of life, surgical scar assessment, and chronic pain. The authors concluded that the results do not support the use of iNPWT for this indication, although the event rate at 30 days was lower than expected.

Singh et al. (2019) performed a meta-analysis of 30 studies that evaluated s-NPWT systems for treating closed wounds. RCTs and observational studies were assessed across specialties, including cardiothoracic, lower extremity, colorectal/abdominal, obstetrics, and vascular surgery. The results demonstrated that the Prevena system performed significantly better at reducing the incidence of surgical site infections compared with traditional and advanced wound dressings. The authors noted limitations, including the heterogeneity of data and lack of high-quality studies for the review.

Strugala and Martin (2017) conducted a meta-analysis of 16 studies (10 RCTs and six observational studies) that compared the prophylactic use of the PICO NPWT system with standard care. Overall, 1,863 individuals were represented in the data. The study reported a significant reduction in surgical site infections, wound dehiscence, and hospital length of stay in individuals treated with NPWT. Similar effects were seen, irrespective of the kind of surgery (orthopedic, abdominal, colorectal, or cesarean section). The inclusion of individuals with incisions that would not be classified as clean is a noted limitation.

Scalise et al. (2016) performed a systematic review of studies that evaluated NPWT for preventing complications of closed surgical incisions. Overall, 18 studies were included: one biomedical engineering study, two animal studies, and 15 human studies (six RCTs, five prospective cohorts, and seven retrospective analyses). Human studies investigated the

outcomes of 1,042 incisions in 1,003 individuals. The review noted a decrease in infections, hematomas, and reoperation rates; however, the results were inconsistent regarding wound dehiscence. Noting limited studies, the authors concluded that further study is needed to identify the proper recommendations for NPWT in this population of individuals.

Pilonidal Disease

There is insufficient clinical evidence that demonstrates the safety and/or efficacy of NPWT systems, including disposable systems, for treating pilonidal disease. Further results from prospective, high-quality studies are needed to determine which population of individuals would benefit from the use of these devices.

Morais et al. (2025) conducted a systematic review and meta-analysis to determine the impact of NPWT on healing in individuals with pilonidal sinus following surgical excision. Overall, there were 10 studies (three RCTs, four retrospective studies, two prospective cohort studies, and one pre-post study) identified; the studies were published in English and included individuals undergoing pilonidal sinus surgical excision who received NPWT for treatment of the surgical wounds by primary or secondary intention, which included a comparative design with data on outcomes of interest. The total population from all the studies was 609 individuals, with 76.6% of male sex and an age range of 14.72 years to 69 years; the studies included children to older adults. Four studies compared treatment of pilonidal sinus following primary wound closure and NPWT, while six studies compared treatment with NPWT in open wounds. The quality of the studies was assessed independently by two authors using the Cochrane Collaboration tool for assessing risk of bias. The authors reported that the studies showed reduction in healing time, recurrence rates, and postoperative pain and higher satisfaction among individuals with the use of NPWT; however, the certainty of the evidence is very low. A meta-analysis of two studies that reported wound healing in days showed that NPWT may reduce the mean time to wound healing compared with any other dressing; however, the evidence is very uncertain. Wound healing measurement that was reported in two studies indicates that NPWT may reduce the mean time to wound healing compared with any other dressing, but the evidence is very uncertain, similar to that for the meta-analysis of seven studies that measured the recurrence rate and showed a 4% recurrence rate in the NPWT group and an 11% recurrence rate in the other dressing group. Limitations noted by the authors include the restriction to only studies published in the English language, lack of blinding of individuals or personnel, lack of analysis or available information in some studies, selective reporting in nine of the 10 studies, and data surrounding benefits showing very low certainty of evidence. The authors concluded that the evidence for this intervention is uncertain and that it is unclear whether NPWT had an influence, when compared with any other dressings, on time to healing, recurrence, pain, or the individuals' experiences. The authors recommended additional high-quality research, with larger sample sizes, to clearly explore the impact of NPWT on pilonidal sinus healing, recurrence, pain, and individuals' satisfaction. The Danne et al. (2017) study, previously included in this policy, was included in this systematic review and meta-analysis.

Hüseyin et al. (2025) conducted a retrospective consecutive cohort study to evaluate the utility of VAC compared with that of standard open wound care in patients undergoing surgery for the treatment of pilonidal sinus disease. The study included 60 patients (mean age, 25.70 ±7.98 years; 76.7% male) who underwent standard pilonidal sinus excision lay-open technique/surgery in a single facility in Istanbul, Turkey, during a 3-year period. The patients were divided into two groups, with 30 patients having had a VAC device applied and 30 patients having received standard open wound care. The VAC and control groups were homogenous for age and sex ($p > 0.05$), and no statistically significant difference was seen between the groups in terms of average values of initial wound size and width ($p > 0.05$). The study excluded anyone under 16 years of age, any cases in which the presacral fascia was affected, and those with abscess or recurrent disease. The VAC dressings were changed every 3 days in the treatment group, while daily dressings were done in those patients in the standard-of-care group. A retrospective analysis of prospectively collected data was performed. The authors reported that there was no statistically significant difference between the VAC group and the control group in terms of preoperative and postoperative infection rates; however, the total recovery time was significantly shorter in the VAC group (21.47 ±4.38 days) than the control group (67.60 ±7.83 days; $p = 0.001$). There was one recurrence that occurred in the VAC group at month 12 post operation and two recurrences (one at 6 months and one at 10 months) in the standard-of-care group. The limitations noted in the study include the small sample size and short follow-up time of 12 months. Other limitations include the retrospective, single-center design and ethnic homogeneity of the patients. The authors concluded that the findings of their study show that the use of VAC in patients undergoing surgery for the treatment of pilonidal sinus disease with the lay-open technique appeared to have the potential to shorten the recovery time; they recommended larger-scale, prospective studies that address the utility of these devices to validate their findings.

Ensor et al. (2024) conducted an RCT to investigate whether NPWT would reduce the rates of surgical wound dehiscence (SWD) compared with conventional passive (CP) dressings for pilonidal sinus disease excisions with off-midline primary closure. The secondary outcomes included participant quality of life and return time to normal activities. Overall, 50 participants from four tertiary hospitals were randomized: 25 to NPWT and 25 to CP. The results demonstrated that the overall dehiscence rate was 42% (21 of 50), with 12 of 25 (48%) for NPWT and nine of 25 (36%) for CP ($p = 0.6$). Five

instances of deep (≥ 5 mm) SWD occurred in each group (p > 0.9). SWD was associated with increased excision dimensions in the NPWT group only (p = 0.03). The median duration to wound healing was equivalent in nondehisced wounds [CP, 21.0 (14.0-29.5) vs NPWT, 21.0 (16.0-24.0) days; p = 0.7]. There were no differences in mean time to returning to school/work (NPWT, 26.1 ±18.2 vs CP, 29.3 ±14.7 days; p = 0.6), sitting normally (NPWT, 22.3 ±16.2 vs CP, 20.1 ±9.4 days; p = 0.7), and returning to physical activity (NPWT, 21.6 ±17.2 vs CP, 40.3 ±2.4 days; p = 0.2). The authors concluded that no difference in the rates of SWD was observed. In addition, NPWT was not found to improve postoperative analgesia use, time to wound healing, participant satisfaction, or return to normal activities. Therefore, NPWT is not recommended to prevent SWD. Limitations of the study include the small sample size, nonblinded design, and potential attrition and performance bias.

A Hayes report on the use of NPWT after surgery for pilonidal disease concluded that the current body of overall very low-quality evidence does not allow for conclusions to be drawn regarding the benefits and potential associated risks of NPWT as a treatment adjunct over standard wound care methods alone. There is a need for additional larger, well-designed studies to evaluate this therapy more thoroughly and to determine which individuals may benefit from NPWT after surgery for pilonidal disease (Hayes, 2020; updated 2023).

Negative Pressure Wound Therapy With Instillation of Wound Solutions

Current published studies on the use of NPWT with instillation and dwell time (NPWTi-d) for the treatment of wounds generally provide low-level evidence with limited quality and wide heterogeneity of the types and locations of wounds included in the studies. Further large, multicenter RCTs, with comparisons to standard NPWT and/or standard wound care, are needed to demonstrate the efficacy of the use of NPWT with instillation of wound solutions to support the use of this treatment regimen.

Milcheski et al. (2025) conducted a single-center, pragmatic, controlled RCT to examine the effectiveness of NPWTi-d compared with that of traditional gauze layer dressing and standard NPWT. The study included 120 adults (mean age, 36.4 years; 79.2% male) with acute traumatic wounds from traffic accidents, urban violence, or falls within 72 hours of presenting to the emergency department. Participants were randomized using the R statistical software to receive NPWTi-d (n = 39; mean age, 37.6 years; 79.5% male), standard NPWT (n = 41; mean age, 34.4 years; 87.8% male), or gauze dressing (n = 40; mean age, 36.4 years; 79.2% male) treatments following surgical debridement of the wound bed and definitive wound closure with DPC, skin grafting, or surgical flaps. Surgical debridement and dressing changes were performed every 3 days in the NPWTi-d group, every 4 days in the NPWT group, and every 2 days in the conventional gauze group, with definitive surgical closure when the wounds were deemed clean by the attending surgeon and tissue cultures were negative for infection. The authors reported that wound closure time was significantly lower in participants who received NPWTi-d (6.1 days) than in those who received standard NPWT (10.0 days) and those in the gauze dressing group (11.7 days). The number of surgical procedures required was also less in the NPWTi-d group (3.0 procedures) than in the NPWT (3.5 procedures) and the gauze dressing groups (6.2 procedures). The authors also reported that the hospital length of stay was shorter in participants in the NPWTi-d group (24.7 days) than in those who received standard NPWT (27.8 days) and those in the gauze dressing group (26.2 days); however, these differences were not statistically significant. Limitations of the study include the single-center, nonblinded design; small sample size; and heterogeneity of the types of wounds included. The authors concluded that NPWTi-d resulted in shorter wound closure time and fewer surgical procedures than standard NPWT or gauze dressing and recommended additional studies in individuals with complex traumatic wounds to corroborate their findings.

De Pellegrin et al. (2023) conducted a systematic review and meta-analysis to compare NPWTi-d with NPWT and standard of care for wound management in orthoplastic surgery. A comprehensive literature search using PubMed, Web of Science, and Cochrane databases was performed, including studies describing the outcomes of NPWTi-d for traumatic/orthopedic injuries. A meta-analysis on the number of surgical debridements as well as the rate of complete wound closure and complications was carried out, although for other outcomes, a descriptive statistic was applied. The risk of bias and quality of evidence were assessed using the Downs and Black Checklist for measuring quality. Overall, 13 studies, with a total number of 871 individuals, were included; the studies showed that NPWTi-d demonstrated higher primary wound closure and lower complication rates (p < 0.05). No difference in the number of surgical procedures required for final wound healing was observed. Moreover, five of six studies showed better results for NPWTi-d when the change of the bioburden and bacterial count of the wound was analyzed. A singular study that investigated the length of the hospital stay in individuals treated with NPWTi-d showed a reduction in the latter. The authors concluded that the present meta-analysis shows that NPWTi-d is superior to NPTW or conventional dressings in orthoplastic wound care management, in terms of complete wound closure rate and the reduced number of complications. Still, the limited quality of the studies analyzed shows that future randomized studies are needed to confirm the benefits; to identify the most appropriate recommendations for using NPWTi-d in orthoplastic surgery; and to investigate the cost-effectiveness of this wound-dressing system. This systematic review and meta-analysis has several limitations. Firstly, the studies using NPWTi-d applied the latter to different anatomical regions of the body, treating wounds of variable size and comparing

different wound closure techniques. Secondly, many different wound care products were used throughout the studies with regard to the control group, which may also have had an influence on the results. Several studies, with a shorter follow-up time and no report on the duration of treatment, may have biased the results by underreporting the complication rate in the long run. Finally, the overall heterogeneity of the available studies and their limited quality made it difficult to properly investigate all outcomes related to these kinds of treatments. In view of this, a meta-analysis could only be performed on several of the outcomes. Future studies are needed to confirm the study findings as well as to better document and quantify the potential benefits of NPWTi-d for wound care in the orthoplastic field.

Diehm et al. (2021) conducted a systematic review that evaluated the use of NPWTi-d for the treatment of acute and traumatic wounds. Ten articles (n = 109 acute and traumatic wounds) met the inclusion criteria. No high-quality RCTs were identified. The majority of studies were retrospective cohort studies, followed by lesser-quality RCTs, comparative studies, and prospective cohorts and two retrospective comparative studies. While NPWTi-d showed promise to be effective in facilitating wound closure and reducing the time for wound closure, the authors found a relatively low level of evidence to support this effect. Large, prospective RCTs are necessary to determine the role of NPWTi-d in the clinical routine for this wound category.

Gabriel et al. (2021) performed a systematic review and meta-analysis of comparative studies that evaluated the effects of NPWTi-d vs those of standard wound care in the treatment of multiple wound types. Overall, 13 studies (n = 720) were included in the analysis. NPWTi-d, when used in conjunction with good clinical practice (e.g., debridement, appropriate antibiotics), was found to be more beneficial than the comparator with respect to the number of surgical debridements during therapy, time to readiness for final wound closure, number of individuals with reduced bacterial bioburden, duration of therapy, and number of wounds closed but similar with respect to hospital length of stay. However, author-noted study limitations, including low-level evidence and high heterogeneity across the individuals and wound population in the studies, suggest cautious interpretation of the results. Large, prospective RCTs are needed to confirm these results.

Kanapathy et al. (2020) conducted a systematic review and meta-analysis of studies that evaluated the efficacy of NPWTi-d. Overall, 13 studies were included, with a total of 624 wounds in 542 individuals, that involved wounds of various etiology. These included surgical wounds (n = 186), trauma wounds (n = 112), pressure ulcers (n = 73), neuropathic wounds (n = 56), infection (n = 28), diabetic ulcers (n = 20), necrotizing fasciitis (n = 19), burns (n = 15), venous wounds (n = 10), and vasculitis (n = 2). Normal saline was the most commonly used instillation solution. The pooled proportion of wounds that achieved complete healing was 93.65%. The authors concluded that although NPWTi-d has versatility to improve wound healing in a broad range of wounds, these conclusions are limited by the lack of high-quality level 1 evidence. The included studies were mostly small retrospective case series in which NPWTi-d was performed on wounds of various etiologies and sizes, with use of different wound closure techniques. RCTs that evaluate the efficacy of NPWTi-d against NPWT or standard dressings are needed.

Clinical Practice Guidelines

American Society of Colon and Rectal Surgeons (ASCRS)

The ASCRS practice parameters for the management of pilonidal disease do not specifically address NPWT as a treatment option (Johnson et al., 2019).

International Working Group on the Diabetic Foot (IWGDF)

The IWGDF evidence-based guidelines on the prevention and management of diabetic foot disease (Chen et al., 2024) make the following recommendations:

- Consider the use of NPWT as an adjunct therapy to standard of care for the healing of postsurgical diabetes-related foot wounds (GRADE strength of recommendation: conditional; quality of evidence: low).
- Do not use NPWT as an adjunct therapy to standard of care for the healing of non–surgically related diabetic foot ulcers (GRADE strength of recommendation: strong; quality of evidence: low).

These recommendations are based on a review by the IWGDF of 19 studies, all of which were thought to be at a moderate to high risk of bias. One study consisted of a population of only nonsurgical wounds, two studies included populations that were a mix of both postsurgical and nonsurgical wounds, and the remaining studies investigated the use of NPWT in postoperative wounds alone. The authors state that overall, the evidence behind the use of NPWT is of low certainty and that there were moderate desirable effects that NPWT may reduce the time to healing in postsurgical wounds, but not in chronic wounds, when provided in addition to the standard of care. According to the authors, these conclusions are consistent with findings from previous guidelines, as no new good-quality evidence has been published since their 2019 guidelines.

National Institute for Health and Care Excellence (NICE)

A NICE guideline concluded that the VAC Veraflo Therapy system (wound instillation with negative pressure therapy) shows promise for treating acute infected or chronic wounds that are not healing. However, there is not enough good-quality evidence to support the case for routine adoption. Further research is recommended to show clinically meaningful benefits for the device compared with NPWT alone (NICE, 2021a).

An amended NICE guideline suggests considering NPWT after cesarean birth for women with a body mass index of 35 kg/m^2 or more to reduce the risk of wound infections. The "consider" recommendation reflects that the evidence of benefit is less certain (NICE, 2021b; updated 2025).

A NICE guideline concluded that PICO negative pressure wound dressings should be considered as an option for closed surgical incisions in people who are at a high risk of developing surgical site infections. They are associated with fewer surgical site infections and seromas than standard wound dressings. The report called out the clinical and statistical heterogeneity of the studies as a limitation. It also noted a wide variation in the risk characteristics of the populations, definition of surgical site infections, how long the dressing was in place, and length and frequency of follow-up (NICE, 2019).

NICE also published a guideline for the assessment and management of complex fractures that states that the use of NPWT after wound excision, if immediate definitive soft tissue cover has not been performed, is not clinically more effective than other dressings. Based on the committee's experience, the committee agreed that (1) compared with other dressings, NPWT could reduce the number of times dressings are changed or supplemented and could reduce the number of associated bedding changes, which would save nursing time, and that (2) NPWT could reduce the pain and discomfort of dressing changes or supplementation (NICE, 2016; updated 2022).

In the NICE guideline that addresses the prevention and management of diabetic foot problems, NICE states that NPWT after surgical debridement for diabetic foot ulcers should be considered on the advice of their multidisciplinary foot care service (2015; updated 2019).

National Pressure Injury Advisory Panel (NPIAP)

NPIAP guidelines recommend considering NPWT as an early adjunct therapy for reducing the size and depth of stage III and IV pressure injuries (NPIAP, 2019).
Strength of evidence:

- Level 1 studies of moderate or low quality providing direct evidence.
- Level 2 studies of high or moderate quality providing direct evidence.
- Most studies have consistent outcomes, and inconsistencies can be explained.

Strength of recommendation: weak positive recommendation.

Society for Vascular Surgery (SVS)

The SVS, in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine, makes the following recommendations on the management of diabetic foot ulcers (Hingorani et al., 2016):

- Standard of care for diabetic foot ulcers will lead to improvement in the majority of cases, and only in those cases without improvement should adjunctive modalities be used.
- For diabetic foot ulcers that fail to demonstrate improvement (> 50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, the guidelines recommend adjunctive wound therapy options, including NPWT. The choice of adjuvant therapy is based on clinical findings. Reevaluation of vascular status, infection control, and off-loading are recommended to ensure optimization before initiation of adjunctive wound therapy (grade 1B; strong recommendation based on moderate-quality evidence).
- The guidelines suggest the use of NPWT 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; weak recommendation based on moderate-quality evidence).

Wound Healing Society (WHS)

The WHS wound care guideline that addresses the treatment of pressure ulcers makes the following recommendations:

- NPWT is a safe and effective treatment for chronic stage III or IV pressure ulcers. The current evidence indicates that NPWT may support pressure ulcer healing by increasing wound perfusion and the formation of granulation tissue and by reducing bacterial load (level I evidence; based on a meta-analysis of multiple RCTs or at least two RCTs supporting the intervention).

- iNPWT may reduce postoperative complications after flap reconstruction for pressure ulcers, specifically surgical site infection and wound dehiscence, in patients at a high risk for surgical complications. The guideline notes that the majority of patients with pressure ulcers would fit the criteria and be considered at high risk for both complications (level III evidence based on suggestive data of proof of principal but lacking sufficient data such as a meta-analysis, RCT, or multiple clinical series).

(Gould et al., 2016; updated 2024)

The WHS guidelines for arterial ulcers state that topical NPWT may be promising for mixed arterial ulcers and that it may have a role as an adjuvant agent, but further study is still required. The WHS states that there are at least theoretical reasons to consider effects on blood flow (positive or negative), but updated evidence has suggested benefits on healing in the setting of peripheral artery disease (level II evidence based on at least one RCT and at least two significant clinical series or expert opinion papers, with literature reviews supporting the intervention) (Federman et al., 2015; updated 2024).

In their guideline that addresses venous ulcers, the WHS states that NPWT may be useful prior to a skin graft/flap by helping promote the development of granulation tissue in the wound base or post operation by preventing shearing and removing exudates. However, its reported experience in venous ulcers is limited (level II evidence based on at least one RCT and at least two significant clinical series or expert opinion papers, with literature reviews supporting the intervention) (Marston et al., 2016).

In their guideline that addresses diabetic foot ulcer treatment, the WHS makes the following recommendations:

- NPWT has been shown to increase the proportion of wounds that heal, decrease in the time to heal, and reduce the incidence of amputations compared with standard wound care in diabetic lower extremity wounds; however, NPWT has not been shown to reduce the incidence of infection (level I evidence based on a meta-analysis of multiple RCTs or at least two RCTs supporting the intervention).
- NPWT with irrigation or instillation has not been shown to improve wound healing or clinical infection in complex diabetic foot ulcers (level I evidence based on a meta-analysis of multiple RCTs or at least two RCTs supporting the intervention).

(Lavery et al., 2016; updated 2024)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

For information on NPWT systems, refer to the following website (use product code OMP): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 3, 2026)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2026	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2026T0594N

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.