Negative Pressure Wound Therapy

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Instructions for Use

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Related Policies

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements
- Skin and Soft Tissue Substitutes

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 apply to all settings.

NPWT, in an outpatient setting or upon 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 indication for NPWT; and
- Documentation that 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 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:
    - Post-operative dehiscence (separation of a previously closed surgical incision) with documentation of a complete wound therapy program, as outlined above; or
    - Open, non-healing amputation site in diabetics; or
    - Post-sternotomy infection (mediastinitis); or
    - Delayed healing or non-healing of 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 installation of wound solutions

Contraindications to NPWT
- Active bleeding or exposed vasculature in wound
- Eschar or necrotic tissue present in wound
- Exposed bone, nerves, or organs in vicinity of wound
- Malignancy present in wound
- Uncontrolled soft tissue infection or osteomyelitis within vicinity of wound
- Presence of an open fistula to body organs or cavities within vicinity of 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 indicate 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

Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

HCPCS Code*	Required Clinical Information
Negative Pressure Wound Therapy (NPWT)	
E2402	Medical notes documenting the following, when applicable: • Diagnosis requiring Negative Pressure Wound Therapy (NPWT) • History of the medical condition(s) requiring treatment • Recent physical exam • Signs and symptoms • Treatments tried, failed, or contraindicated; include the dates, duration of treatment, and reason for discontinuation • Wound stage/size/location/measurements • Wound type (post-surgical, venous stasis, decubitus ulcer, diabetic neuropathic ulcer) • Date(s) of surgery including debridement

HCPCS Code*	Required Clinical Information
Negative Pressure Wound Therapy (NPWT)	

	• The date the NPWT [wound vacuum-assisted closure (VAC)] was started
	• Favorable wound environment has been maintained with:
	  ○ Appropriate dressing/dressing changes
	  ○ Adequate nutritional status
	  ○ Management of incontinence, if applicable
	  ○ Wound is free of the following:
	  ▪ Active bleeding or exposed vasculature in the wound
	  ▪ Necrotic tissue
	  ▪ Exposed bone, nerves, or organs in vicinity of wound
	  ▪ Malignancy present in wound
	  ▪ Open fistula to an organ or body cavity within the vicinity of the wound
	  ▪ Uncontrolled soft tissue infection or osteomyelitis within vicinity of wound
	• If member is diabetic, the member is maintained on a diabetic management program
	• Member is turned and repositioned with the presence of a Stage III or IV pressure ulcer
	• If applicable, NPWT (wound VAC) has been used previously on the same type of wound with a favorable clinical response; please explain

*For code descriptions, refer to the Applicable Codes section.

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; often requires soft-tissue coverage (i.e., flap).
- IIIC: Arterial injury requiring repair. (Gustilo and Anderson, 1976; Gustilo et al., 1984)

National Pressure Injury Advisory Panel (NPIAP) 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 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 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 may apply.

Coding Clarification: Suction pumps and dressing 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 the 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, 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 utilized based on a number of factors.

Kirsner et al. (2019) conducted a multicenter, randomized, comparative-efficacy study in patients 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 versus traditional NPWT (t-NPWT) over a 12-week treatment period or up to confirmed healing. Randomized by wound type and size, 164 patients with non-infected diabetic foot ulcers and venous leg ulcers were included. The intention to treat population was composed of 161 patients (101 with venous leg ulcers, 60 with diabetic foot ulcers) and 115 patients completed follow-up (64 in the s-NPWT group and 51 in the t-NPWT group) (PP population). Primary endpoint analyses on wound area reduction demonstrated statistically significant reduction in favor of s-NPWT ($p = 0.003$) for the PP population and for the ITT

population (p < 0.001). Changes in wound depth (p = 0.018) and volume (p = 0.013) were also better with s-NPWT. Faster wound closure was observed in the ITT population. Wound closure occurred in 45% of patients in the s-NPWT group vs. 22.2% of patients in the t-NPWT group (p = 0.002). Median estimate of the time to wound closure was 77 days for s-NPWT. No estimate could be provided for t-NPWT. 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 versus t-NPWT in terms of wound progression toward healing over the treatment period. This study is 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.

Anghel and Kim (2016) conducted a comprehensive literature review of NPWT versus standard care for various wound types. A total of 26 publications were included. The authors tabulated and discussed the level of evidence, wound type studied, reported outcomes and impact and key findings. The authors concluded that NPWT has a role in managing chronic, complex and infected wounds. Randomized controlled trials (RCTs) validating superiority of NPWT in certain patient populations are cited. They also noted that more robust, randomized, prospective studies are needed to support its expanding use.

Pressure Ulcers

Sahin et al. (2021) conducted a RCT on the effectiveness of NPWT compared to wet-to-dry dressing in pressure injuries (PIs). Thirty patients with stage 3 and 4 pressure injuries were divided into two groups: NPWT group and the wet-to-dry-dressing group. Following three rounds of treatment in all patients, data were collected using a three-dimensional wound measurement (3DWM) device, pressure ulcer scale for healing (PUSH) tool and patient identification form. The data revealed significant granulation tissue formation in the experimental group (p < .05) with significant wound shrinkage (p < .05) and a decrease in PUSH tool scores (p < .05). Patient wounds were assessed with the PUSH Tool and 3DWM system which showed device measurements were correlated with PUSH tool findings (p < .05) a significant correlation noted between device-measured granulation findings and PUSH tool score results of the experimental group's third measurements (p < .05). The authors concluded NPWT is an effective treatment measure for pressure injuries. Limitations include small sample size and short-term follow-up. The authors recommend future studies with larger sample sizes that monitor treatment efficacy until the wound has completely healed.

Vig et al. (2011) published evidence-based recommendations for the use of NPWT in chronic wounds. Based on a systematic review of the literature, the international panel of experts recommended the following regarding pressure ulcers:

- NPWT may be used until surgical closure is possible/desirable.
- Alternatively, NPWT should be considered to achieve closure by secondary intention.
- NPWT should be used to reduce wound dimensions.
- NPWT should be used to improve the quality of the wound bed.

Neuropathic Ulcers

A systematic review and meta-analysis performed by Wang et al. (2022) compared the efficacy and safety of the NWPT with moist wound care (MWC) in the treatment of diabetic foot ulcers (DFUs). A total of 10 RCTs (619 patients in NPWT group and 625 in MWC group) were included in the review, and 8 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 significantly lower risk of non-closure of the wound (risk ratio [RR] = 0.74, 95% confidence interval [CI]: 0.63–0.87; p = .001), lower average wound area (standard mean difference = -0.80, 95% CI: -1.54 to -0.06; p = .034), more wound area decrease (standard mean difference = 0.81, 95% CI: 0.36–1.26; p = .001), an increase in the appearance rate of granulation tissue (RR = 1.61, 95% CI: 1.07–2.41; P-0.021), and lower risk of amputation or resection (RR = 0.70, 95% CI: 0.50–0.99; p = .045), were shown for the NPWT group when compared to 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 = .05). The authors concluded that NPWT could accelerate the wound healing process and decrease the risk of post-treatment amputation or resection, without any additional frequency of adverse events when compared with MWC, in patients with DFUs. Limitations include the addition of RCTs with relatively low-quality and small sample sizes to the study. The authors recommend more high-quality RCTs are needed to identify the treatment efficacy of NPWT compared with 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 time to wound closure was shorter for patients receiving NPWT. (Hayes, 2016; updated 2021)

Rys et al. (2020) conducted a systematic review and meta-analysis of 16 observational studies (n = 1882 managed with NPWT) evaluating the efficacy and safety of NPWT in patients with diabetic foot ulcers. In the NPWT-treated patients, ulcers were larger (average size range 6.6-27.9 cm^2), as compared with controls (≤ 3 cm^2). The pooled results showed healing and major amputation in 51% and 5% of NPWT patients, respectively. A meta-analysis of four comparative studies revealed lower risk of major amputation in NPWT-treated patients. The pooled results for healing rate and risk of any amputation were inconclusive due to large heterogeneity between studies. These results support earlier RCT data that NWPT 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 standard care or other adjuvant therapies in the healing of diabetic foot wounds. Eleven 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)

Liu et al. (2017) performed a systematic review and meta-analysis to assess the safety and efficacy of NPWT in the treatment of diabetic foot ulcers. A total of eleven RCTs (n = 1044) were included. Compared with standard dressing changes, NPWT had a higher rate of complete healing, shorter healing time, greater reduction in ulcer area and depth and fewer amputations.

Anghel and Kim (2016) conducted a comprehensive literature review of NPWT versus standard care for various wound types. Seven of the studies investigated complicated wounds in diabetic patients, either following amputations, significant surgical intervention or chronic stable ulcers. The consensus was that NPWT is safe, effective and reduces operative interventions for complicated wounds in diabetic patients.

Zhang et al. (2014) conducted a meta-analysis to evaluate the safety and effectiveness of NPWT for diabetic foot ulcers. Eight RCTs (n = 669) were included. Compared with non-NPWT treatments, NPWT resulted in a significantly higher proportion of healed ulcers, more reduction of ulcer area, fewer major amputations and shorter time to wound healing.

Vig et al. (2011) published evidence-based recommendations for the use of NPWT in chronic wounds. Based on a systematic review of the literature, the international panel of experts recommended the following regarding diabetic foot ulcers:

- NPWT must be considered as an advanced wound care therapy for postoperative grade 2 and 3 diabetic feet without ischemia.
- NPWT must be considered to achieve healing by secondary intention.
- Alternatively, NPWT should be stopped when wound has progressed suitably to be closed by surgical means.
- NPWT should be considered in an attempt to prevent amputation or re-amputation.

Venous Insufficiency Ulcers

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 patients who received NPWT than among those who did not. (Hayes, 2016; updated 2021)

Vig et al. (2011) published evidence-based recommendations for the use of NPWT in chronic wounds. Based on a systematic review of the literature, the international panel of experts recommended the following regarding venous leg ulcers:

- If first-line therapy (compression) is not efficacious, NPWT should be considered to prepare the wound for surgical closure as part of a clinical pathway.

Open Surgical Wounds

A Hayes evidence report summarized the publications related to the use of NPWT in the outpatient setting for 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)

Anghel and Kim (2016) conducted a comprehensive literature review of NPWT versus standard care for various wound types. Four studies evaluated the use of NPWT for split thickness skin graft retention, with 3 specifically investigating the use in acute injury or burn patients. All found that NPWT resulted in better outcomes than standard dressing. The use of NPWT after skin-grafted free muscle flaps resulted in reduced inflammatory response and edema formation.

A Cochrane systematic review concluded that there is some evidence that NPWT may reduce time to healing following a punch skin graft transplant. (Dumville et al., 2015)

Azzopardi et al. (2013) systematically reviewed the evidence for the perioperative application of NPWT to split-thickness skin grafts. Thirty-eight studies were included. The authors reported two complementary trends explaining the mechanisms whereby grafts benefit from NPWT: active stimulation of epithelial mitosis and prevention of complications. NPWT also promotes microcirculatory flow and stimulates angiogenesis. This study concluded that NPWT increases quantity and quality of graft take compared to traditional bolster dressings. The advantages are increased in irregularly contoured, technically difficult wounds and suboptimal recipient wound beds.

Pan et al. (2013) performed a systematic review and meta-analysis to evaluate the efficacy of NPWT compared to conventional therapy in the treatment of post-sternotomy infections. Twelve cohort studies (n = 873) were included. The authors reported that wound closure was obtained more frequently in the NPWT group when compared to conventional therapy. NPWT was associated with a significant reduction in length of stay compared with standard of care.

Damiani et al. (2011) performed a meta-analysis of six studies evaluating NPWT for treating patients with infected sternal wounds. Of 321 patients, 169 received NPWT and 152 received conventional therapy. The authors reported that NPWT significantly reduced hospital length of stay but did not have a significant impact on mortality when compared to standard therapy.

Krug et al. (2011) published evidence-based recommendations for the use of NPWT in reconstructive surgery. Based on a systematic review of the literature, the international panel of experts made the following recommendations:

- NPWT must be considered to improve the rate of graft success.
- NPWT should be considered in wounds/patients with high risk of graft loss.
- As an initial bolster, NPWT should be left undisturbed for 3–7 days post-grafting split-thickness skin graft.
- When NPWT is used as bolster continuous pressure level should be used.

In a multicenter RCT, Armstrong et al. (2005) investigated whether NPWT improved the rate of wound healing after partial foot amputation in diabetic patients. The study enrolled 162 patients who were randomly assigned to receive NPWT (n = 77) or standard moist wound care (n = 85). Wounds were treated until healing or completion of the 112-day period of active treatment. Patients in the NPWT group experienced a higher proportion of healed wounds, faster healing rates and faster granulation tissue formation rates than those in the control group. The frequency and severity of adverse events were similar in both treatment groups.

Open Fractures

Haidari et al. (2021) performed a systematic review to assess the role of NPWT in the management of soft tissue defects in patients 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, varying from one to seven weeks. Four studies took repeated microbial swabs during subsequent NPWT dressing changes. One study reported newly detected pathogens in 23% of the included patients and three studies did not find new pathogens. The authors concluded 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 could be performed. The authors note 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 patients 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 (SSI) 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 = 1377) were included. Study sample sizes ranged from 40 to 586 participants. 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 six 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 on the incidence of deep infections/osteomyelitis after open tibial fractures. Ninety-three 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 compared to the control group (22%). NPWT was also associated with less bacterial colonization (6.9% vs. 34%) of wounds compared to the control group. Five patients (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 days vs. 9.8 days).

Tansarli et al. (2014) performed a meta-analysis of four RCTs (n = 367) evaluating the incidence of SSI in patients with open wounds following fracture stabilization. Infection rates in patients whose wounds were treated with vacuum-assisted closure (n = 196) were reduced by 53% when compared to nonvacuum closure (n = 171).

Krug et al. (2011) published evidence-based recommendations for the use of NPWT in traumatic wounds and reconstructive surgery. Based on a systematic review of the literature, the international panel of experts recommended that NPWT be considered for open fracture wounds as a bridge to definitive closure when primary closure is not possible after or in between debridements.

In a prospective randomized trial, Stannard et al. (2009) evaluated the impact of NPWT on deep infections in patients with severe open fractures. Fifty-nine patients with 63 severe high-energy open fractures were enrolled in the study, with data available on 58 patients with 62 open fractures. Twenty-three patients with 25 fractures were randomized to the control group and underwent irrigation and debridement followed by standard dressing, with repeat irrigation and debridement every 48-72 hours until wound closure. Thirty-five patients were randomized to the NPWT group and had identical treatment except that NPWT was applied to the wounds between irrigation and debridement procedures until wound closure. In the control group, 2 patients developed acute infections (8%) and 5 developed delayed infections (20%), for a total of 7 deep infections (28%). NPWT patients developed 0 acute infections and 2 delayed infections (5.4%), for a total of 2 deep infections (5.4%).

Closed Surgical Incisions

There is insufficient clinical evidence demonstrating 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 risk of bias to support routine use. Further results from prospective, high-quality studies are needed to determine which patient population would benefit from the use of these devices.

A Hayes Evolving Evidence Review found minimal support for the use of PICO single-use 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 single-use NPWT in this population; however, study conclusions were inconsistent. (Hayes, 2021d; updated 2023)

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 to NPWT over standard sterile dressing driven by a lower rate of superficial infections; however, recent RCT evidence has not confirmed these findings and uncertainty remains. Significant heterogeneity exists between patient populations, underlying reason for abdominal surgery, and treatment characteristics within the included body of evidence making it difficult to discern which patients might most benefit from this form of prophylaxis. (Hayes, 2021e; updated 2023)

Several Hayes abstract-only reviews evaluated NPWT for treating clean, closed incisions following orthopedic procedures. A report on ankle and lower leg incisions found NPWT was well-tolerated, and the results related to overall wound complications were similar to those experienced by patients treated with standard dressings. Short-term clinical benefit, in terms of pain and function, were reported; however, these differences were not sustained in the long-term (Hayes, 2021a). A report on primary hip and knee arthroplasty procedures generally found a decrease in noninfectious wound complications (e.g., seroma, exudate, leakage) when NPWT was used, compared with standard wound care; however, there was minimal support for the use of NPWT to reduce the number of postoperative SSIs in the general population of primary arthroplasty patients. Clinical benefit may be more pronounced in at-risk populations (e.g., obesity, smoking, diabetes) (Hayes, 2021b). A report on revision hip and knee arthroplasty procedures found a decrease in SSIs and overall complications when NPWT was used compared with conventional or antimicrobial dressings alone. The benefits were most pronounced in patients with a higher risk profile (e.g., obesity, prior periprosthetic joint infection, and inflammatory arthritic conditions) (Hayes, 2021c). The report noted that critical appraisal of full text studies is required to draw evidence-based conclusions about the effectiveness, efficacy, or safety of the technology for these indications and the quality and strength of the evidence supporting the conclusions.

An updated Cochrane review (Norman et al., 2020), assessed the effects of NPWT for preventing SSI in wounds healing through primary closure. This update added 15 new RCTs, resulting in a total of 44 RCTs (n = 7447). Studies evaluated NPWT in the context of a wide range of surgeries including orthopedic, obstetric, vascular and general procedures. Most studies had unclear or high risk of bias for at least one key domain. The review concluded that there were no clear difference in 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 where 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 is probably no difference in pain between NPWT and standard dressings after surgery for lower limb fracture (moderate-certainty evidence). In a fourth update of this review (Norman et al. 2022) added 18 new RCTs to the study for a total of 62 RCTs of 13,340 participants. 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 unclear or high risk of bias for at least one key domain. The results concluded there is no difference in wound dehiscence (moderate-certainty evidence) for people with primary closure of their surgical wound treated prophylactically with NPWT following surgery compared with people treated with standard dressings; however, NPWT probably results in fewer surgical site infections (SSIs) than standard dressings. There may be reduced risk of death after surgery for 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 where 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 when compared with standard wound dressing in obese women undergoing cesarean delivery. The Tuuli study (included in the 2022 Cochrane review above) was terminated after 1624 of 2850 participants were recruited when a planned interim analysis showed increased adverse events in the NPWT group and futility for the primary outcome of reduced SSIs.

In the WHIST multicenter RCT, Costa et al. (2020) assessed outcomes of incisional NPWT (n = 785) versus standard wound dressing (n = 763) on deep SSI after surgery for lower limb fractures associated with major trauma. At 30 days, deep SSI occurred in 5.84% (45 of 770 patients) of the incisional NPWT group and in 6.68% (50 of 749 patients) 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 patient-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 incisional NPWT 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 evaluating single-use NPWT systems for treating closed wounds. RCTs and observational studies were assessed across specialties including cardiothoracic, lower extremity, colorectal/abdominal, obstetrics and vascular surgery. Results demonstrated that the Prevena system performed significantly better at reducing the incidence of SSIs in comparison to traditional and advanced wound dressings. Author noted limitations include 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 6 observational studies) comparing prophylactic use of the PICO NPWT system with standard care. A total of 1863 patients were represented in the data. The study reported significant reduction in SSI, wound dehiscence and hospital length of stay in patients treated with NPWT. Similar effects were seen irrespective of the kind of surgery (orthopedic, abdominal, colorectal or cesarean section). The inclusion of patients with incisions that would not be classified as "clean" is a noted limitation.

Scalise et al. (2016) performed a systematic review of studies evaluating NPWT for preventing complications of closed surgical incisions. Eighteen studies were included: 1 biomedical engineering study, 2 animal studies and 15 human studies (6 RCTs, 5 prospective cohorts, 7 retrospective analyses). Human studies investigated the outcomes of 1042 incisions on 1003 patients. The review noted a decrease in infections, hematomas and re-operation rates; however, results were inconsistent regarding wound dehiscence. Noting limited studies, the authors concluded that further study is needed to identify proper recommendations for NPWT in this patient population.

Pilonidal Disease

There is insufficient clinical evidence demonstrating 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 patient population would benefit from the use of these devices.

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 more thoroughly evaluate this therapy more thoroughly and to determine which patients may benefit from NPWT after surgery for pilonidal disease. (Hayes, 2020; updated 2023)

Danne et al. (2017) conducted a retrospective chart analysis of pilonidal sinus healing using NPWT versus alginate or gauze dressings. Thirty-two patients received NPWT and 30 received daily dressings. The median time to healing in the group receiving daily dressings was 10 weeks compared to 8 weeks in the group receiving NPWT. Among patients who healed, the difference in average time to healing was 5.2 weeks. However, the differences were not statistically significant. Study limitations include retrospective design and small patient numbers. Larger prospective, RCTs are needed to evaluate the efficacy of NPWT for treating pilonidal disease.

Biter et al. (2014) evaluated the role of NPWT in treating pilonidal sinus disease. Forty-nine patients were randomly assigned to NPWT (n = 24) for 2 weeks or standard open wound care (n = 25) after surgical excision. NPWT resulted in a higher wound healing rate in the first 2 weeks after excision. However, no significant benefit of NPWT was seen with respect to time to complete wound healing and time to resume daily life activities. The authors noted that more research is needed before NPWT can be implemented as a standard treatment in patients with pilonidal sinus disease. This study is limited by the small patient numbers, short follow-up and lack of blinding.

NPWT With Instillation of Wound Solutions

Diehm et al. (2021) conducted a systematic review evaluating the use of NPWT with instillation and dwell time (NPWTi-d) for the treatment of acute and traumatic wounds. Ten articles (n = 109 acute and traumatic wounds) met inclusion criteria. No high-quality RCTs were identified. The majority of studies were retrospective cohort studies, followed by lesser-quality RCTs, comparative studies or prospective cohorts, and 2 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 evaluating the effects of NPWTi-d versus standard wound care in the treatment of multiple wound types. Thirteen 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 number of surgical debridements during therapy, time to readiness for final wound closure, number of patients 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

patient and wound population heterogeneity across studies, suggested 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 evaluating the efficacy of NPWTi-d. Thirteen studies were included with a total of 624 wounds in 542 patients involving wounds of various etiology. These included surgical wounds (n = 186), trauma (n = 112), pressure ulcers (n = 73), neuropathic (n = 56), infection (n = 28), diabetic ulcers (n = 20), necrotizing fasciitis (n = 19), burns (n = 15), venous (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 where NPWTi-d was performed on wounds of various etiologies and sizes along with different wound closure techniques. RCTs evaluating the efficacy of NPWTi-d against NPWT or standard dressings are needed.

Clinical Practice Guidelines

American Society of Colon and Rectal Surgeons (ASCRS)

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)

IWGDF evidence-based guidelines on the prevention and management of diabetic foot disease (Rayman et al., 2020) make the following recommendations:

- Consider the use of NPWT to reduce wound size, in addition to best standard of care, in patients with diabetes and a post-operative (surgical) wound on the foot. (GRADE Strength of recommendation: Weak; Quality of evidence: Low)
- We suggest not using NPWT in preference to best standard of care in non-surgical diabetic foot ulcers. (GRADE Strength of recommendation: Weak; Quality of evidence: Low)

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 (BMI) of 35 or more to reduce the risk of wound infections. The “consider” recommendation reflects that the evidence of benefit is less certain. (NICE, 2021b)

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 high risk of developing SSIs. They are associated with fewer SSIs and seromas compared with 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, the definition of SSIs, how long the dressing was in place and the length and frequency of follow up. (NICE, 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)

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. Choice of adjuvant therapy is based on clinical findings. Re-evaluation 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)

WHS wound care guidelines make the following recommendations:

- Consider using NPWT for stage III or IV pressure ulcers that fail to progress in healing with conventional therapy. Current evidence indicates that NPWT may support pressure ulcer healing by increasing wound perfusion and formation of granulation tissue and by reducing bacterial load (Gould et al., 2016). Level I evidence – a meta-analysis of multiple RCTs or at least two RCTs supporting the intervention.
- NPWT may be useful prior to a skin graft/flap by helping promote the development of granulation tissue in the wound base, or postoperatively by preventing shearing and removing exudates. However, its reported experience in venous ulcers is limited (Marston et al., 2016). Level II - at least one RCT and at least two significant clinical series or expert opinion papers with literature reviews supporting the intervention.
- NPWT has been shown to increase the proportion of wounds that heal and the rate of wound healing compared with standard wound care in diabetic lower extremity wounds (Lavery et al., 2016). Level I evidence – a meta-analysis of multiple RCTs or at least two RCTs supporting the intervention.

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 January 2, 2024)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2023T0594J]

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Policy History/Revision Information

Date	Summary of Changes

04/01/2024	**Documentation Requirements**
	• Updated list of required clinical information:
	  ○ Added:
	  ▪ Diagnosis requiring Negative Pressure Wound Therapy (NPWT)
	  ▪ History of the medical condition(s) requiring treatment
	  ▪ Recent physical exam
	  ▪ Signs and symptoms
	  ▪ Treatments tried, failed, or contraindicated; include the dates, duration of treatment, and reason for discontinuation
	  ▪ Wound is free of active bleeding or exposed vasculature in the wound
	  ▪ Wound is free of exposed bone, nerves, or organs in vicinity of wound
	  ○ Removed “current prescription from physician”
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version SURGERY 110.10

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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