

Negative Pressure Wound Therapy (for Tennessee Only)

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[Instructions for Use](#)

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<p>Related Community Plan Policies</p> <ul style="list-style-type: none"> Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements (for Tennessee Only) Skin and Soft Tissue Substitutes (for Tennessee Only)
<p>Commercial Policy</p> <ul style="list-style-type: none"> Negative Pressure Wound Therapy
<p>Medicare Advantage Coverage Summary</p> <ul style="list-style-type: none"> Wound Treatments

Application

This Medical Policy applies to Medicaid only plans in the state of Tennessee.

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 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 wounds
 - Pilonidal disease
- Disposable/single-use NPWT systems

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

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 Ulcer Advisory Panel (NPUAP) Staging System (NPUAP,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 federal, state, or contractual requirements 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 (K0743–K0746) apply to devices other than negative pressure wound therapy. For use of K0743–K0746, refer to the Coverage Determination Guideline titled [Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements \(for Tennessee Only\)](#).

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

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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 treatment for acute and chronic wounds that uses the controlled application of subatmospheric pressure to the surface of a wound to remove exudate and debris. The system includes dressings, a suction pump, tubing and a collection chamber. The area is sealed with an adhesive film, and the pump delivers a controlled negative pressure across the surface of the wound. The goal of NPWT is to facilitate wound healing by removing exudate, promoting the formation of new blood vessels, reducing bacterial colonization, promoting granulation of the wound bed and providing a bridge to surgical closure. NPWT is intended as an adjunct treatment

for wounds that do not respond to conventional treatment such as debridement, pressure relief and infection control (Rhee et al., 2014).

Clinical Evidence

Despite a lack of strong evidence to support its use, NPWT has gained wide acceptance for a variety of wounds.

An ECRI clinical comparison report evaluated the current state of the evidence for several NPWT systems (ECRI, 2020).

Kirsner et al. (2019) conducted a multicenter, randomized, comparative-efficacy study in patients with venous leg ulcers (VLUs) or diabetic foot ulcers (DFUs). 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 DFUs and VLUs were included. The intention to treat population was composed of 161 patients (101 with VLUs, 60 with DFUs) 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.

An Agency for Healthcare Research and Quality (AHRQ) report was unable to draw conclusions about the efficacy or safety of NPWT for the treatment of chronic wounds in the home setting due to insufficient evidence. Though NPWT has been used across the wound care spectrum, the authors concluded that significant research gaps remain. Standardization of wound care research protocols, such as providing consistency in comparator groups, robust randomized study designs, larger trials and common definitions of outcomes, would be helpful in providing evidence to inform decisions about the use of NPWT (Rhee et al., 2014).

Pressure Ulcers

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

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).

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 2020).

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

Blume et al. (2008) evaluated the safety and efficacy of NPWT compared with advanced moist wound therapy (AMWT) to treat diabetic foot ulcers. The multicenter RCT (n=342) randomly assigned patients to NPWT or AMWT. A greater proportion of foot ulcers achieved complete ulcer closure with NPWT than with AMWT within the 112-day active treatment phase. NPWT patients experienced significantly fewer secondary amputations. Treatment-related complications such as infection, cellulitis and osteomyelitis were similar at 6 months.

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 2020).

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.

Surgical Wounds

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.

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

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.

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

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.

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).

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 SSIs 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 Wounds

There is insufficient clinical evidence demonstrating the safety and/or efficacy of NPWT systems, including disposable systems, for treating closed wounds. 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 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, 2021).

An updated Cochrane review (Webster et al., 2019) assessed the effects of NPWT for preventing SSI in wounds healing through primary closure. For this update, 25 intervention trials were added for a total of 30 intervention trials (n=2957). Surgeries included abdominal and colorectal (n=5); caesarean section (n=5); knee or hip arthroplasties (n=5); groin surgery (n=5); fractures (n=5); laparotomy (n=1); vascular surgery (n=1); sternotomy (n=1); breast reduction mammoplasty (n=1); and mixed (n=1). Despite the addition of 25 trials, results were consistent with the earlier review. The evidence was judged to be of low or very low certainty for all outcomes. Consequently, uncertainty remains about whether NPWT compared with a standard dressing reduces or increases the incidence of important outcomes such as mortality, dehiscence or seroma. Given the widespread use of NPWT for SSI prophylaxis, there is a need for larger, well-designed and well-conducted trials to evaluate the effects of newer NPWT products designed for use on clean, closed surgical incisions.

A NICE report 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).

Singh et al. (2019) performed a meta-analysis of 30 studies evaluating single-use NPWT systems for treating closed wounds. Randomized controlled trials 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 SSIs, 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 and to determine which patients may benefit from NPWT after surgery for pilonidal disease (Hayes, 2020).

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.

Professional Societies

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).

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 is 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).

National Pressure Ulcer Advisory Panel (NPUAP)

NPUAP guidelines recommend considering NPWT as an early adjunct therapy for reducing the size and depth of Stage III and IV pressure injuries (NPUAP, 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

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, see the following website (use product code OMP):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm>. (Accessed February 9, 2021)

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Policy History/Revision Information

Date	Summary of Changes
08/01/2021	<p>Template Update</p> <ul style="list-style-type: none">Reformatted policy; transferred content to new template <p>Definitions</p> <ul style="list-style-type: none">Updated definition of “National Pressure Ulcer Advisory Panel (NPUAP) Staging System (NPUAP, 2019)” <p>Supporting Information</p> <ul style="list-style-type: none">Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current informationRemoved <i>CMS</i> sectionArchived previous policy version CS157TN.D

Instructions for Use

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