Negative Pressure Wound Therapy - Wound Vac AHM

Clinical Indications for Wound Vac

- Negative pressure wound therapy (NPWT) pumps are considered medically necessary, when 1 or more of the following of the following criteria is met
  - Use of a NPWT in the home setting is considered medically necessary when ALL of the following are met
    - Member has 1 or more of the following
      - Member has 1 or more of the following ulcers that has been present for 30 days
        - Chronic Stage III or IV pressure ulcer
        - Neuropathic ulcer (e.g., diabetic ulcer)
        - Venous or arterial insufficiency ulcer
        - Chronic ulcer of mixed etiology
    - Member has 1 or more of the following wounds and continuation of the inpatient treatment plan is occurring in the home
      - Chronic Stage III or IV pressure ulcer
      - Neuropathic ulcer (e.g., diabetic ulcer)
      - Venous or arterial insufficiency ulcer
      - Chronic ulcer of mixed etiology
      - The member has complications of a surgically created wound (e.g., dehiscence) or a traumatic wound (e.g., pre-operative flap or graft), other than complications resulting in an open abdomen
  - A complete wound therapy program described below has been considered and ruled out prior to application of NPWT. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of ALL of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT
    - Application of dressings to maintain a moist wound environment
    - Debridement of necrotic tissue if present
    - Documentation of evaluation, care, and wound measurements by a licensed medical professional
- Evaluation of and provision for adequate nutritional status
  - For the appropriate ulcer or wound type criteria **1 or more** of the following are required
    - For Stage III or IV pressure ulcers where **ALL** of the following are met
      - The member has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis. A group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis [A]
      - The member has been appropriately turned and positioned
    - For neuropathic (e.g., diabetic) ulcers **ALL** of the following are met
      - The member has been on a comprehensive diabetic management program
      - Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities
    - For venous insufficiency ulcers **ALL** of the following are met
      - Compression bandages and/or garments have been consistently applied
      - Leg elevation and ambulation have been encouraged
    - For chronic ulcers of mixed etiology member has tried and failed treatment listed above
    - For the acute surgically created wound there is medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (e.g., other conditions of the member that will not allow for healing times achievable with other topical wound treatments).
  - **Use of a NPWT in an Inpatient Setting** is considered medically necessary when **1 or more** of the following are met
    - An ulcer or wound is encountered in the inpatient setting and, after wound treatments for the types of ulcers above have been tried or considered and ruled out, it is necessary to initiate NPWT and **ALL** of the following are met
      - Member has **1 or more** of the following ulcers that has been present for 30 days
        - Chronic Stage III or IV pressure ulcer
        - Neuropathic ulcer (e.g., diabetic ulcer)
        - Venous or arterial insufficiency ulcer
        - Chronic ulcer of mixed etiology
    - A complete wound therapy program described below has been considered and ruled out prior to application of NPWT. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of **ALL** of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT
• Application of dressings to maintain a moist wound environment
• Debridement of necrotic tissue if present
• Documentation of evaluation, care, and wound measurements by a licensed medical professional
• Evaluation of and provision for adequate nutritional status
• For the appropriate ulcer type criteria 1 or more of the following are required
  • For Stage III or IV pressure ulcers ALL of the following are met
    ▪ The member has been appropriately turned and positioned
    ▪ The member has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis. A group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis
    ▪ The member's moisture and incontinence have been appropriately managed
  • For neuropathic (e.g., diabetic) ulcers ALL of the following
    ▪ The member has been on a comprehensive diabetic management program
    ▪ Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities
  • For venous insufficiency ulcers ALL of the following are met
    ▪ Compression bandages and/or garments have been consistently applied
    ▪ Leg elevation and ambulation have been encouraged
    ▪ For chronic ulcers of mixed etiology member has tried and failed treatment listed above
    ▪ The member has complications of a surgically created wound (e.g., dehiscence) or a traumatic wound (e.g., pre-operative flap or graft), other than complications resulting in an open abdomen, where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (e.g., other conditions of the member that will not allow for healing times achievable with other topical wound treatments)
  • Continued treatment with a NPWT pump is considered medically necessary when ALL of the following are met
    ▪ Wound(s) being treated with the NPWT pump is assessed by a licensed professional and supervise or directly perform the NPWT dressing changes
    ▪ Document changes in the ulcers dimensions and characteristics on a monthly basis
• Note: Staging of pressure ulcers used in this policy is as follows
• Suspected Deep Tissue: Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.
• Stage I: Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.
• Stage II: Partial thickness loss of dermis presenting as a shallow open ulcer with red or pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.
• Stage III: Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining or tunneling.
• Stage IV: Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.
• Unstageable: Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown, or black) in the wound bed.

**Indications Not Considered Medically Necessary**

• NPWT pump and supplies will be considered as not medically necessary when any of the following apply
  • Any measurable degree of wound healing has failed to occur over the prior month
    ▪ There must be documentation of quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented, over a specified time interval. The recorded wound measurements must be consistently and regularly updated and must have demonstrated progressive wound healing from month to month
  • Four months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound
    ▪ The medical necessity of NPWT beyond 4 months will be given individual consideration based upon required additional documentation. Refer to the Medical Director
  • In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued
  • Once equipment or supplies are no longer being used for the member, whether or not by the physician's order
  • When criteria under section on Continued Medical Necessity above, cease to be met
• NPWT is contraindicated in the presence of the following
  • Cancer present in the wound
  • The presence in the wound of necrotic tissue with eschar, if debridement is not attempted
  • The presence of a fistula to an organ or body cavity within the vicinity of the wound
  • Untreated osteomyelitis within the vicinity of the wound
• NPWT pumps must be capable of accommodating more than 1 wound dressing set for multiple wounds on a member. Therefore, more than 1 NPWT pump billed per member for the same time period is considered not medically necessary
• The use of non-powered (mechanical) NPWT devices (e.g., the Smart Negative Pressure [SNaP] Wound Care System) is considered investigational because their effectiveness has not been established.
• The use of single-use NPWT devices (e.g., PICO Single Use Negative Pressure Wound Therapy System; Prevena Incision Management System) is considered investigational for all indications (e.g., wound care and keloid scarring) because of insufficient evidence of their effectiveness.

Guide for Supplies

• Up to a maximum of 15 dressing kits per wound per month is considered medically necessary unless there is documentation that the wound size requires more than 1 dressing kit for each dressing change
• Up to a maximum of 10 canister sets per month is considered medically necessary unless there is documentation showing a large volume of drainage (greater than 90 ml of exudate per day)
• For high volume exudative wounds, a stationary pump with the largest capacity canister must be used. Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) is not considered medically necessary

Evidence Summary

Background

• NPWT is considered experimental and investigational for the treatment of open abdominal wounds (e.g., abdominal compartment syndromes, traumatic injuries, and severe intra-abdominal sepsis), pilonidal sinus disease, deep sternal wound infection, and all other indications other than those noted above because its effectiveness for these indications has not been established.
• The use of chemotherapeutic agents (e.g. doxycycline and insulin) in continuous-instillation NPWT experimental and investigational because its effectiveness has not been
established. This guideline is based in part upon Medicare DMERC medical necessity criteria for negative pressure wound therapy (NPWT) pumps.

- Negative pressure wound therapy is the controlled application of subatmospheric pressure to a wound using an electrical pump to intermittently or continuously convey subatmospheric pressure through connecting tubing to a specialized wound dressing which includes a resilient, open-cell foam surface dressing, sealed with an occlusive dressing that is meant to contain the subatmospheric pressure at the wound site and thereby promote wound healing. Drainage from the wound is collected in a canister.

- Negative pressure wound therapy has been used to promote healing of chronic wounds and pressure ulcers (decubitus ulcers) by creating controlled negative pressure over the wound that is thought to increase local vascularity and oxygenation of the wound bed, reduce edema by evacuating wound fluid, and remove exudate and bacteria.

- More than a dozen systematic evidence reviews produced by independent organizations have questioned the quality of the evidence supporting the use of NPWT, including systematic evidence reviews published by the Cochrane Collaboration (Evans and Land, 2001; Wasiak and Cleland, 2007; Ubbink et al, 2008), Washington State Department of Labor and Industries (2003), Canadian Coordinating Office for Health Technology Assessment (Fisher and Brady, 2003), Australian Safety and Efficacy Register of New Intervventional Procedures - Surgical (Pham et al, 2003), NHS Quality Improvement Scotland (NHS QIS, 2003), Centre for Clinical Effectiveness (Higgins, 2003), Agency for Healthcare Research and Quality (Samson et al, 2004)


- Control of intra-abdominal fluid secretion, facilitation of abdominal exploration, and preservation of the fascia for abdominal wall closure is a major challenge in the management of patients with an open abdomen. Vacuum-assisted therapy has been reported to help meet the challenges of managing the open abdomen and may be useful in patients with abdominal compartment syndromes, traumatic injuries, and severe intra-abdominal sepsis. In a review on the management of patients with open abdomen, Kaplan (2004) concluded that controlled clinical studies are needed to establish the safety and effectiveness of this treatment approach and to facilitate the development of treatment guidelines to help manage an increasingly common group of patients who might benefit from this treatment approach.

- A systematic evidence review by the National Institute for Health and Clinical Excellence (NICE, 2009) found inadequate evidence for the use of NPWT in open abdominal wounds. The NICE assessment concluded that current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen is inadequate in quality and quantity. There has been concern about the occurrence of intestinal fistulae associated with this procedure but there is currently no evidence about whether NPWT is the cause.
• Schimmer and colleagues (2007) stated that there are many primary modalities for managing deep sternal wound infection (DSWI) following cardiac surgery, namely surgical debridement with primary re-closure in conjunction with irrigation, VAC, and primary or delayed flap closure. These researchers examined if there is consensus on the primary management of DSWI using one method as a single line therapy or a combination of these procedures. Therefore, a questionnaire with regards to the primary treatment modalities of DSWI was distributed to all 79 German heart surgery centers.

• All replied to the questionnaire -- VAC is used in 28/79 (35 %) heart centers as the 'first-line' treatment, 22/79 (28 %) perform primary reclosure in conjunction with a double-tube irrigation/suction system, and in 29/79 (37 %) clinics both treatment options were used according to intra-operative conditions. Mostly, as a primary management of DSWI two treatment modalities are mainly in use: primary reclosure coupled with a double-tube suction/irrigation system and VAC. The current understanding is based purely on retrospective studies, not evidence-based medicine. Since prospective randomized controlled trials (RCTs) have not yet been performed, controlled clinical trials comparing these treatment modalities are pivotal to define evidence for patients presenting with DSWI.

• Morris et al (2007) noted that although NPWT appears effective, it remains unknown if it is more effective than other wound closure techniques. In addition, although many uncontrolled, non-randomized studies describing the effectiveness of this therapy have been published, few prospective RCTs have been conducted. Small sample sizes, variable outcome measures across studies, and significant methodological problems in the available RCTs further limit the conclusions that can be drawn regarding the relative effectiveness of vacuum-assisted wound closure. Analysis of these data provided weak evidence to suggest that NPWT is superior to saline gauze dressings in healing chronic wounds. The authors concluded that RCTs comparing healing, costs of care, patient pain, and quality-of-life outcomes of this treatment to non-gauze type dressings and other treatment modalities are needed.

• Gregor et al (2008) examined the clinical effectiveness and safety of negative NPWT compared with conventional wound therapy; RCTs and non-RCTs comparing NPWT and conventional therapy for acute or chronic wounds were included in this review. The main outcomes of interest were wound-healing variables. After screening 255 full-text articles, 17 studies remained. In addition, 19 unpublished trials were found, of which 5 had been prematurely terminated. Two reviewers independently extracted data and assessed methodological quality in a standardized manner. Seven RCTs (n = 324) and 10 non-RCTs (n = 278) met the inclusion criteria. The overall methodological quality of the trials was poor. Significant differences in favor of NPWT for time to wound closure or incidence of wound closure were shown in 2 of 5 RCTs and 2 of 4 non-RCTs. A meta-analysis of changes in wound size that included 4 RCTs and 2 non-RCTs favored NPWT (standardized mean difference: RCTs, -0.57; non-RCTs, -1.30).

• The authors concluded that although there is some indication that NPWT may improve wound healing; the body of evidence available is insufficient to clearly prove an additional clinical benefit of NPWT. Furthermore, the large number of prematurely terminated and unpublished trials is reason for concern.
• Vikatmaa et al (2008) conducted a systematic review of the literature on the safety and effectiveness of NPWT for problematic wounds. A total of 14 RCTs were included. Trials included patients with: (i) pressure wounds, (ii) post-traumatic wounds, (iii) diabetic foot ulcers, and (iv) miscellaneous chronic ulcers. Only 2 trials were classified as high quality studies, whereas the remaining were classified as having poor internal validity. The authors concluded that (i) reliable evidence on the effectiveness of NPWT is scarce, (ii) tentative evidence indicates that the effectiveness of NPWT is at least as good as or better than current local treatment for wounds, and (iii) the need for large high-quality randomized studies is apparent.

• Blume et al (2008) evaluated the safety and clinical efficacy of NPWT compared with advanced moist wound therapy (AMWT) (predominately hydrogels and alginates) to treat foot ulcers in diabetic patients in a multi-center randomized controlled trial (n = 342). The mean age was 58 years and 79 % of subjects were male. Complete ulcer closure was defined as skin closure (100 % re-epithelization) without drainage or dressing requirements. Patients were randomly assigned to either NPWT or AMWT (predominately hydrogels and alginates) and received standard off-loading therapy as needed. The trial evaluated treatment until day 112 or ulcer closure by any means. Patients whose wounds achieved ulcer closure were followed at 3 and 9 months. Each study visit included closure assessment by wound examination and tracings.

• A greater proportion of foot ulcers achieved complete ulcer closure with NPWT (73 of 169, 43.2 %) than with AMWT (48 of 166, 28.9 %) within the 112-day active treatment phase (p = 0.007). The Kaplan-Meier median estimate for 100 % ulcer closure was 96 days (95 % confidence interval [CI]: 75.0 to 114.0) for NPWT and not determinable for AMWT (p = 0.001). Patients who received NPWT experienced significantly (p = 0.035) fewer secondary amputations. The proportion of home care therapy days to total therapy days for NPWT was 9,471 of 10,579 (89.5 %) and 12,210 of 12,810 (95.3 %) for AMWT. In assessing safety, no significant difference between the groups was observed in treatment-related complications such as infection, cellulitis, and osteomyelitis at 6 months. The authors concluded that NPWT appears to be as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers.

• The Centers for Medicare and Medicaid Services (CMS) partnered with the Agency for Healthcare Research and Quality (AHRQ) and commissioned a review of NPWT devices. AHRQ contracted with the ECRI Institute Evidence-based Practice Center to perform the review.

• A technology assessment report on NPWT (Sullivan et al, 2009) prepared for the Agency for Healthcare Research and Quality found that systematic reviews of NPWT reveal the following important points about the current state of the evidence on this technology: (i) all of the systematic reviews noted the lack of high-quality clinical evidence supporting the advantages of NPWT compared to other wound treatments; the lack of high-quality NPWT evidence resulted in many systematic reviewers relying on low-quality retrospective studies to judge the efficacy of this technology, (ii) no studies directly comparing different NPWT components (e.g., foam versus gauze dressings) were identified by any of the reviewers, and (iii) NPWT must be evaluated according to wound
type; wound healing varies according to the type of wound being treated and NPWT benefits described for one wound type cannot be assumed to apply to other wound types.

- The assessment stated that the available evidence cannot be used to determine a significant therapeutic distinction of a NPWT system. In addition, due to the lack of studies comparing one NPWT system to another NPWT system the severity of adverse events for 1 NPWT system compared to another could not be determined. The report concluded, Clinical research on NPWT capable of indicating if any one NPWT system or component provides a significant therapeutic distinction requires study design and conduct that will minimize the possibilities for bias. Important study design features that were not typically reported such as concealment of allocation, reporting of randomization methods, use of power analysis to ensure adequate study size, blinding wound assessors, and reporting of complete wound healing data will improve the internal validity and the informativeness of the studies.

- Negative pressure wound therapy uses a reticulated sponge and subatmospheric pressure to facilitate healing of a variety of wounds. The therapy appears to assist wound healing by decreasing wound bacterial burden and edema while facilitating granulation tissue formation. The latest development in NPWT allows clinicians to instill continuously a treatment solution and suspension into the wound. A variety of wound chemo-therapeutic agents such as insulin, which acts as a growth factor, may prove helpful in this aspect. Scimeca and colleagues (2010a) presented a case report in which insulin was used as a chemo-therapeutic agent in continuous-instillation NPWT. To the authors' knowledge, this is the first report in the literature describing this method of delivery. Furthermore, Scimeca et al (2010b) described a real-time streaming therapy of a variety of wound chemo-therapeutic agents through NPWT.

- Doxycycline, which acts as a competitive inhibitor of matrix metalloproteinases and tumor necrosis factor alpha and further decreases inflammation through the reduction of nitrous oxide production, may prove helpful when delivered in this manner. To the authors' knowledge, this is the first report in the literature describing this method of delivery of doxycycline. The clinical value of chemo-therapeutic agents in continuous-instillation NPWT needs to be ascertained in randomized, controlled clinical trials.

- A non-powered (mechanical) NPWT device, the Smart Negative Pressure (SNaP) Wound Care System from Spiracur, is a class II device that received 510(k) marketing clearance from the Food and Drug Administration in 2010 and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, subacute wounds and diabetic and pressure ulcers. The lack of well-designed comparative studies with large number of individuals using the non-powered NPWT system is insufficient to draw conclusions about its impact on health outcomes with the device and in comparison with current care.

- The European Pressure Ulcer Advisory Panel's clinical practice guideline on pressure ulcer treatment (2009) recommended conventional NPWT therapy, but did not mention non-powered NPWT.

- In a systematic review, Roberts et al (2012) determined the comparative safety and effectiveness of NPWT versus alternate temporary abdominal closure (TAC) techniques in critically ill adults with open abdominal wounds. These researchers reviewed
published and unpublished comparative studies. They searched MEDLINE, PubMed, EMBASE, Scopus, Web of Science, the Cochrane Database, the Center for Reviews and Dissemination, clinical trials registries, and bibliographies of included articles. Two authors independently abstracted data on study design, methodological quality, patient characteristics, and outcomes. Among 2,715 citations identified, 2 RCTs and 9 cohort studies (3 prospective/6 retrospective) met inclusion criteria. Methodological quality of included prospective studies was moderate.

- One RCT observed an improved fascial closure rate (relative risk [RR], 2.4; 95% CI: 1.0 to 5.3) and length of hospital stay after addition of retention sutured sequential fascial closure to the Kinetic Concepts Inc. (KCI) vacuum-assisted closure (VAC). Another reported a trend toward enhanced fascial closure using the KCI VAC versus Barker's vacuum pack (RR, 2.6; 95% CI: 0.95 to 7.1). A prospective cohort study observed improved mortality (RR, 0.48; 95% CI: 0.25 to 0.92) and fascial closure (RR, 1.5; 95% CI: 1.1 to 2.0) for patients who received the ABThera versus Barker's vacuum pack. Another noted a reduced arterial lactate, intra-abdominal pressure, and hospital stay for those fitted with the KCI VAC versus Bogota bag.

- Most included retrospective studies exhibited low methodological quality and reported no mortality or fascial closure benefit for NPWT. The authors concluded that limited prospective comparative data suggested that NPWT versus alternate TAC techniques may be linked with improved outcomes. Moreover, they stated that the clinical heterogeneity and quality of available studies precluded definitive conclusions regarding the preferential use of NPWT over alternate TAC techniques.

- Guidance from the National Institute for Health and Clinical Excellence (NICE, 2013) stated that current evidence on the safety and efficacy of NPWT for the open abdomen is adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance. The guidance stated that NPWT for the open abdomen may be used to manage open abdominal wounds in which the gut and other intraperitoneal organs are exposed.

- In a Cochrane review, Dumville and Munson (2012) evaluated the effectiveness of NPWT for people with partial-thickness burns. For this third update we searched the Cochrane Wounds Group Specialised Register (searched May 18, 2012); the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library 2012, Issue 5); Ovid MEDLINE (2010 to week 2 of May 2012); Ovid MEDLINE (in-process & other non-indexed citations May 17, 2012); Ovid EMBASE (2010 to week 19 of 2012); and EBSCO CINAHL (2010 to May 16, 2012). All RCTs and controlled clinical trials (CCTs) that evaluated the safety and effectiveness of NPWT for partial-thickness burns were selected for analysis. Two review authors used standardized forms, and extracted the data independently. They assessed each trial for risk of bias, and resolved differences by discussion. One RCT, that was an interim report, satisfied the inclusion criteria.

- These investigators undertook a narrative synthesis of results, as the absence of data and poor reporting precluded them from carrying out any formal statistical analysis. The trial was at high-risk of bias. The authors concluded that there was insufficient evidence available to permit any conclusions to be drawn regarding the use of NPWT for treatment of partial-thickness burn wounds.
• The PICO single-use negative pressure wound therapy device (Smith & Nephew, Inc., Andover, MA) is a single-use, canister-free, negative pressure wound therapy device. It is marketed for use in the following types of wounds: chronic; acute; traumatic; subacute and dehisced wounds; partial-thickness burns; ulcers (e.g., diabetic or pressure); flaps and grafts; and closed surgical incisions. The PICO system contains a disposable, 1-button pump, coupled with an advanced dressing that negates the need for a canister. The pump is pocket-sized and the dressing can be worn up to 7 days.

• Fracalvieri et al (2012) stated that keloid scarring represents a pathological healing where primary healing phenomenon is deviated from normal. PICO is a single-use negative pressure wound therapy system originally introduced to manage open or just closed wounds. PICO dressing is made of silicone, and distributes an 80 mmHg negative pressure across wound bed. Combination of silicon layer and continuous compression could be a valid method to manage keloid scarring. Since November 2011, 3 patients were enrolled and evaluated before negative pressure treatment, at end of treatment (1 month) and 2 months later, through Vancouver scar scale (VSS), visual analog scale (VAS) and a scoring system for itching. Ultrasound (US) and color-power-Doppler (CPD) examination was performed to evaluate thickness and vascularization of the scar.

• One patient was discharged from study after 1 week. In last 2 patients, VSS, VAS and itching significantly improved after 1 month therapy and the results were stable after 2 months without any therapy. At end of therapy, the appearance of palisade vessels disappeared in both cases at CPD exam; US showed a thickness reduction (average of 43.8 %). The authors proposed a well-tolerated, non-invasive treatment to manage keloid scarring. They stated that prospective studies are needed to confirm these preliminary findings.

References


Appendix

- **Specifications of Equipment and Supplies:**

  NPWT is provided with an integrated system of components. This system contains a pump, dressing sets and a separate collection canister. Wound suction systems that do not contain all of the required components are not classified as NPWT. See below for component specifications.

- **Contraindications for Negative Pressure Wound Therapy (NPWT):**

  NPWT is contraindicated in the presence of any of the following:
  - Cancer present in the wound
  - Inadequately debrided wounds; granulation tissue that will not form over necrotic tissue
  - Presence of untreated coagulopathy
  - The presence in the wound of necrotic tissue with eschar, if debridement is not attempted
  - The presence of a fistula to an organ or body cavity within the vicinity of the wound
  - Untreated osteomyelitis or spesis within the vicinity of the wound.

- **List of Negative Pressure Wound Therapy (NPWT) Devices**

  - ActiV.A.C. Therapy Unit
  - Engenex Advanced NPWT System
• Exusdex wound drainage pump
• EZCARE Negative Pressure Wound Therapy
• Genadyne A4 Wound Vacuum System
• InfoV.A.C. Therapy Unit
• Invia Liberty Wound Therapy
• Invia Vario 18 ci Wound Therapy
• Medela Invia Liberty pump
• Mini V.A.C.
• NPD 1000 Negative Pressure Wound Therapy System
• Prodigy NPWT System (PMS-800 and PMS-800V)
• PRO-II
• PRO-I
• RENASYS EZ Negative Pressure Wound Therapy
• SVEDMAN and SVED Wound Treatment Systems
• V.A.C. ATS
• V.A.C. Freedom
• V.A.C. Freedom
• V.A.C. Therapy Unit
• V.A.C. (Vacuum Assisted Closure)
• V1STA Negative Pressure Wound Therapy
• Venturi Negative Pressure Wound Therapy
• These devices have U.S. Food and Drug Administration 510(k) clearance for marketing in the United States. This list is not all-inclusive.

**Documentation Requirements:**

- Information describing the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the member's medical record and be available for review upon request. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).

- Information describing the wound evaluation and treatment, recorded in the member's medical record, must indicate regular evaluation and treatment of the beneficiary's wounds, as detailed in the Policy Section. Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly. The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound
measurement as documented in the member's medical record, in order to determine whether the equipment and supplies continue to be medically necessary.

- (The supplier need not view the medical records in order to bill for continued use of NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the supplier. However, the member's medical records may be requested in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement.)

- When billing for NPWT, an ICD-9-CM diagnosis code (specific to the 5th digit or narrative diagnosis), describing the wound being treated by NPWT, must be included on each claim for the equipment and related supplies.

- The medical record must include a statement from the treating physician describing the initial condition of the wound (including measurements) and the efforts to address all aspects of wound care listed in the Policy Section. For each subsequent month, the medical record must include updated wound measurements and what changes are being applied to effect wound healing. Month-to-month comparisons of wound size must compare like measurements i.e. depth compared to depth or surface area compared to surface area.

- If the initiation of NPWT occurs during an inpatient stay, in order to accurately account for the duration of treatment, the initial inpatient date of service must be documented. This date must be available upon request.

- When NPWT therapy exceeds 4 months on the most recent wound, individual consideration for one additional month at a time may be sought using the appeals process. Information from the treating physician's medical record, contemporaneous with each requested one-month treatment time period extension, must be submitted with each appeal explaining the special circumstances necessitating the extended month of therapy. Note, this policy provides coverage for the use of NPWT limited to initiating healing of the problem wounds described in the Policy section of this CPB rather than continuation of therapy to complete healing since there is no published medical literature demonstrating evidence of a clinical benefit for the use of NPWT to complete wound healing. Therefore, general, vague or nonspecific statements in the medical record such as "doing well, want to continue until healed" provide insufficient information to justify the need for extension of treatment. The medical record must provide specific and detailed information to explain the continuing problems with the wound, what additional measures are being undertaken to address those problems and promote healing and why a switch to alternative treatments alone is not possible.

- When billing for quantities of canisters greater than those described in the Policy Section as the usual maximum amounts, there must be clear and explicit information in the medical record that justifies the additional quantities.
Footnotes

[A] The member's moisture and incontinence have been appropriately managed [ A in Context Link 1 ]

Codes

CPT® or HCPCS: 97605, 97606, A6550, E2402, G0456