Medical Policy

Subject:	Vacuum Assisted Wound Therapy in the Outpatient Setting		
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Description/Scope

This document addresses the use of vacuum assisted wound therapy (also known as negative pressure wound therapy or NPWT) in the outpatient setting for a variety of wounds such as ulcers related to pressure sores, venous or arterial insufficiency or neuropathy. These devices have several attributes that are used to differentiate them from each other, including being stationary vs. portable, if they are operated electrically vs. mechanically, and if they are reusable or disposable. Each device has some combination of these attributes.

Note: For additional information regarding wound care, please refer to:

- CG-MED-71 Chronic Wound Care in the Home or Outpatient Setting
- SURG.00011 Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting

Position Statement

Note: In some circumstances, the use of this treatment modality when initiated in the inpatient setting may not meet criteria for use in the outpatient setting.

Medically Necessary:

Electrically powered vacuum assisted wound therapy is considered **medically necessary** when the individual meets **all** of the criteria (A, B, and C) below:

A. A complete wound care program, which meets ALL of the requirements below, has been tried:
    1. Documentation in the individual's medical record of evaluation, care, and wound measurements by a licensed medical professional; **and**
    2. Application of dressings to maintain a moist environment; **and**
    3. Debridement of necrotic tissue if present; **and**
    4. Evaluation of and provision for adequate nutritional status; **and**
    5. Underlying medical conditions (e.g., diabetes, venous insufficiency) are being appropriately managed; **and**

B. An eligible condition is documented (individual must meet **one** or more of the following):
    1. Stage III or IV pressure ulcers (see key terms below) at initiation of vacuum assisted wound therapy, in individuals who meet ALL of the following:
        a. The individual has been appropriately turned and positioned; **and**

   b. The individual has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (no special support surface is required for ulcers not located on the trunk or pelvis); **and**
   c. The individual's moisture and incontinence have been appropriately managed; **or**
2. Neuropathic ulcers in individuals who meet BOTH of the following:
   a. The individual has been on a comprehensive diabetic management program; **and**
   b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **or**
3. Ulcers related to venous or arterial insufficiency, in individuals who meet ALL of the following:
   a. Compression bandages and/or garments have been consistently applied; **and**
   b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **and**
   c. For initiation of therapy in the home setting, presence of the ulcer for at least 30 days; **or**
4. Dehisced wounds or wound with exposed hardware or bone; **or**
5. Post sternotomy wound infection or mediastinitis; **or**
6. Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment; **and**

C. The wound to be treated is free from all of the following absolute contraindications to vacuum assisted wound therapy:
1. Exposed anastomotic site; **or**
2. Exposed nerves; **or**
3. Exposed organs; **or**
4. Exposed vasculature; **or**
5. Malignancy in the wound; **or**
6. Necrotic tissue with eschar present; **or**
7. Non-enteric and unexplored fistulas; **or**
8. Untreated osteomyelitis.

Continued use of electrically powered vacuum assisted wound therapy is considered **medically necessary** when:

A. Weekly assessment of the wound's dimensions and characteristics by a licensed health care professional is documented; **and**
B. Progressive wound healing is demonstrated.

Not Medically Necessary:

Continued use of electrically powered vacuum assisted wound therapy is considered **not medically necessary** when the continuation of treatment criteria above have not been met.

Investigational and Not Medically Necessary:

Electrically powered vacuum assisted wound therapy is considered **investigational and not medically necessary** for all other applications not meeting the medical necessity criteria above, including when any absolute contraindications to vacuum assisted wound therapy are present.

Non-electrically powered vacuum assisted wound therapy (for example, the SNaP™ Wound Care Device) is considered **investigational and not medically necessary** for all conditions.

Rationale

Electrically Powered Negative Pressure Wound Therapy (NPWT)

Because of the multimodality nature of wound care, ideally randomized trials are required to isolate the contribution of any one component. Additionally, trials should include clinically relevant endpoints, such as the percent of individuals with complete healing or the percent of individuals that require skin grafting, and stratify results according to wound type and size. There have been no published randomized trials (RCTs) that meet these criteria. Several small randomized trials of negative pressure wound therapy (NPWT) using electrically powered devices have been published, all of which reported positive results according to some parameter of wound healing (Armstrong, 2005; Blume, 2008; Canaino, 2005; De Franzo, 2001; Doss, 2002; Eginton, 2003; Stannard, 2009). There are methodological flaws with all of these articles. Additionally, many case series have reported positive results (Baillot, 2010; Ford, 2002; Garner, 2001; Hersh, 2001; Moisidis, 2004; Moues, 2004; O'Connor, 2005), and vacuum assisted wound therapy has been widely accepted and implemented in the medical community on a national basis.

Stannard and others (2012) reported the results of a prospective industry sponsored randomized trial of NPWT as a prophylactic method of avoiding infections and wound dehiscence in high-risk extremity fractures below the knee. The study involved 249 subjects older than 18 years of age with 263 high-energy tibial plateau, pilon (distal tibial), and calcaneus fractures undergoing open surgical repair. Subjects were randomized to receive post-operative NPWT (n=130) or standard wound dressings (n=119). The authors reported no significant differences in time to discharge between groups. There was a borderline statistically significant difference (p=0.049) between groups with regard to post-operative infections, with the control group developing 5 (4%) acute and 18 (15%) late infections and the NPWT group having 1 (0.7%) acute and 13 (9%) delayed infections. Wound dehiscence was reported in 20 (16.5%) of control subjects and 12 (8.6%) of NPWT subjects (p=0.044). This study was not blinded. The results are promising, but this is the first study evaluating NPWT as prophylactic treatment to prevent infection and wound dehiscence of high-risk surgical incisions. Further study is warranted to confirm these findings and identify which postoperative wounds are appropriate for prophylactic NPWT.

Rui-Feng and others published the results of a prospective RCT investigating the impact of NPWT for serious dog bite wounds of the extremities (2016). The study included a total of 580 subjects aged 18-94 years old randomly divided into three groups. Subjects in group A (n=329) received open wound therapy. The remaining subjects (n=251) were randomly divided into two subgroups, with group B (n=123) treated with 125 mm Hg NPWT and group C (n=128) receiving 75 mm Hg NPWT. The authors noted that antibiotics were not given prophylactically, but used only where systemic wound infection was suspected. No cases of rabies or deaths were reported. The wound infection rates of groups A, B, and C were 9.1%, 4.1%, and 3.9%, respectively. The mean infection times were 26.3 hours, 159.8 hours, and 166.4 hours, respectively. Mean recovery times for infected subjects were 19.2 days, 13.2 days, and 12.7 days, respectively. For non-infected subjects, the mean recovery times were 15.6 days, 10.1 days, and 10.5 days, respectively. No differences were reported with regard to infection times or healing times between the two NPWT groups. It should be noted that statistics were not provided for between-group comparisons. The authors concluded that subjects with serious dog bite lacerations on limbs could benefit from

NPWT when compared with open wound therapy. While these results are promising, further data including comparative statistics would be helpful to better understand the benefits of NPWT in the treatment of dog bite wounds.

A large RCT, the WOLFF trial, compared NPWT (n=226) vs. standard care (n=234) for the treatment of severe open fracture of the lower extremities (Costa, 2018). At 12 months after randomization, self-reported Disability Rating Index (DRI) was not significantly different between groups (p=0.13). Additionally, no significant differences between groups were noted with regard to the number of deep surgical infections (7.1 vs. 8.1, p=0.64). The authors concluded the study did not support the use of NPWT for the treatment of severe open fractures of the lower extremity. However, this study alone is not sufficient evidence to conclude that NPWT is not appropriate for severe open fracture wounds.

The results of WHIST RCT by Costa and colleagues (2020) involved 1548 subjects who underwent surgical repair of lower limb fractures caused by major trauma. Subjects were assigned to undergo postoperative treatment with either incisional NPWT (n=785) or standard care (n=763). The authors reported that at 30 days post procedure, the incidence of deep surgical site infection was 5.84% in the NPWT group vs. 6.68% in the control group (odds ratio [OR], 0.87; p=0.52). Additionally, no significant differences in the incidence of deep surgical site infections were reported at 90 days (11.4% in the NPWT group vs. 13.2% in the control group (OR, 0.84; p=0.32). No significant differences at any time point were reported for 5 pre-specified secondary outcomes, including patient-reported disability, health-related quality of life, surgical scar assessment, chronic pain at 3 and 6 months, or other local wound healing complications at 30 days. The authors concluded, "The findings do not support the use of incisional negative pressure wound therapy in this setting, although the event rate at 30 days was lower than expected."

In 2017 Smid and others published the results of a meta-analysis of studies involving NPWT for obese women following cesarean delivery. The study included 10 studies, 5 of which were RCTs. They reported no differences in primary composite outcome among subjects treated with NPWT (16.8%) vs. those treated with standard therapy (17.8%; risk ratio (RR), 0.97).

Seidel (2020) published the results of a large blinded RCT on NPWT for the treatment of subcutaneous abdominal wound healing impairment (SAWHI) after surgery without fascia dehiscence. Subjects were randomized to receive treatment for 42 days with either NPWT (n=256) or conventional therapy (n=251). A total of 507 subjects were included in the intent-to-treat (ITT) analysis. The mean time to complete, sustained, and verified wound closure within 42 days was significantly shorter in the NPWT group (36.1 days vs. 39.1 days; p<0.001). However, due to the fact that 71.2% of the wounds (NPWT, 64.1%; conventional therapy, 78.5%) were not closed within 42 days, it was not possible to calculate the median time to wound closure. In the NPWT group, more wounds were sutured, whereas in the conventional therapy arm, slightly more wounds healed by secondary intention, but this difference was not statistically significant. No wound recurrences after complete sustained healing were reported. Total reduction of wound surface area and wound volume within 42 days calculated from width and length was significantly greater in the NPWT arm vs. the conventional therapy group (p=0.007 and p=0.002, respectively). No difference between groups was reported with regard to adverse events in the modified ITT analysis. However, in the analysis excluding unauthorized treatment changes, the risk of adverse events was slightly higher in the NPWT group (relative risk, [RR], 1.20). In the treatment compliant population, adverse events occurred only in the NPWT group (RR, 1.51). The authors concluded that NPWT is an effective treatment option for SAWHI after surgery, but noted that it is associated with a higher rate of wound-related adverse events. Overall, this study supports the use of NPWT for complicated surgically created wounds.

The safety and efficacy of NPWT in pediatric populations has been addressed in multiple studies (Baharestani, 2007; Caniano, 2005; Chen, 2017; Gabriel, 2009; Li, 2013; Mouës, 2007; Petkar, 2011; Visser, 2017; Yang 2017). This body of evidence includes the treatment of acute and chronic wounds, burns, full-thickness wounds, surgical site infections, soft tissue abscesses, and severe lower leg injuries. At this time, the available evidence shows that the use of NPWT in pediatric populations is both safe and efficacious, and that age appears to have no impact on treatment outcomes.

Portable, Battery Powered, Single Use (Disposable) Vacuum Assisted Wound Therapy Devices

Vacuum assisted wound therapy may also be applied using battery powered portable devices. The available peer-reviewed published evidence addressing the use of such devices is limited to a few small studies. Pellino (2013) described a small Italian study comparing the use of the PICO portable negative pressure wound therapy device to conventional gauze dressings in 30 subjects with stricturing Crohn's disease (CD) undergoing surgical treatment. Subjects were assigned in a nonrandom fashion to treatment with either PICO (n=13) or conventional dressings (n=17). Each subject completed a 3-month follow-up period. The results indicate that the PICO group experienced significantly fewer postoperative wound complications (p=0.001) and surgical site infections (p=0.017) compared with the control group. The authors also report that the PICO group had significantly shorter hospital stays (p=0.0007). They concluded that the data suggest that PICO allows faster discharge by reducing the incidence of surgical site infection and wound-related complications in selected individuals undergoing surgical intervention for stricturing CD.

Hudson and others (2013) reported a small case series using a PICO NPWT prototype to manage 20 subjects with various types of wounds. Subjects were only treated for a maximum treatment period of 14 days to allow for longitudinal assessment of negative pressure and leak rates during therapy. Sixteen (80%) subjects had closed surgical wounds, 2 (10%) subjects had traumatic wounds, and 2 (10%) subjects received meshed split thickness skin grafts. Mean study duration was 10.7 days (range: 5-14 days) and the mean dressing wear time per individual was 4.6 days (range: 2-11). A total of 55% of wounds had closed by the end of the 14-day study or earlier, with a further 40% of wounds progressing to closure. Real-time pressure monitoring showed continuous delivery of NPWT throughout the study period. The authors concluded that the use of the disposable PICO system was feasible and the data confirmed the ability of the device to function consistently over the expected wear time. However, it should be noted that the study period was significantly shorter than what would be expected during actual clinical care. Data collection over a longer period of time is warranted.

Another short-term study was reported by Pellino and others (2014). In this small nonrandomized, unblinded controlled study, 30 subjects undergoing surgical intervention for stricturing Crohn's disease were assigned to receive postoperative treatment with the PICO system (n=13) or standard postoperative wound care (n=17). Group assignments were made on the basis of whether or not subjects meeting the study criteria were willing to receive treatment with the PICO system or not. PICO group subjects received treatment with 125 mmHg for 7 days postoperatively. An additional cycle of PICO treatment of unspecified duration was provided in some subjects. The number of subjects receiving additional PICO treatment was not provided. No significant differences between groups were reported with regard to mean operative time, type of surgical procedures, or duration of antibiotic administration. However, a significant difference between groups, in favor of the PICO group, was reported with regard to the incidence of postoperative wound complications and infections at 3 months postoperatively. Only 1 subject in the PICO group developed a surgical site infection vs. 8 in the control group (p=0.042). The duration of

length of stay (LOS) also favored the PICO group vs. controls (mean LOS 7.5 ± 1.8 vs, 10.3 ± 1.6, respectively; p=0.0007). Unfortunately, time to complete healing was not reported in this study. However, while these results are promising, they should be viewed with care, as the study was conducted using a methodology that failed to isolate a wide variety of confounding variables, allowing the results to be significantly influenced by multiple sources of bias.

In a similar study, Selvaggi (2014) reported a nonrandomized, unblinded controlled study involving 50 sequential subjects undergoing surgical intervention for stricturing Crohn's disease assigned to receive postoperative treatment with the PICO system (n=25) or standard postoperative wound care (n=25). As with the Pellino study described above, the PICO group subjects received treatment for 7 days postoperatively. However, the PICO device was set to deliver 80 mmHg of negative pressure vs. 125 mmHg. Also as in the Pellino study, an additional cycle of PICO treatment of unspecified duration was provided in some subjects. The number of subjects receiving additional PICO treatment was not provided. The follow-up period was 3 months. As with the earlier study, LOS was significantly shorter in this study for the PICO group vs. controls (mean LOS 7 ± 2 vs. 12 ± 2, respectively; p=0.0001). The PICO group was reported to have significantly fewer surgical site complications, specifically with relation to seroma formation (p=0.008) and surgical site infection (p=0.004). The control group had a significantly higher rate of early readmission vs. the PICO group (24% vs. 0%, p=0.02).

Karlakki and colleagues (2016) reported an open-label RCT of the PICO system (n=108) vs. standard care (n=107) in subjects undergoing elective primary total hip and knee arthroplasties. The primary outcome was to measure the impact of the PICO system on wound healing and effect on LOS with a follow-up time of 6 weeks. More subjects in the control group had higher grade exudate vs. the PICO group (16% vs. 4%, p=0.007). With regard to LOS, the PICO group had a smaller range vs. controls (10 days vs. 61 days, p=0.003). The comparison of mean LOS for the intent-to-treat population was not significant, with 3.8 days in the PICO group vs. 4.7 days for controls (p=0.07). In the control group, 9 subjects (8.4%) developed wound complications vs. 2 PICO group subjects (2.0%) following discharge (no p-value provided). Overall there was a four-fold reduction in post-operative wound complications in the study group vs. the control group, but this was not found to be significant (p=0.06).

In 2017 Gupta reported the results of a retrospective non-blinded comparative study involving subjects who had received Whipple procedures and were subsequently treated with PICO (n=36) vs. standard care (n=25). The authors reported significantly fewer surgical site infections in the PICO group vs. controls (3 vs. 15, p=0.01). There was negative correlation between surgical site infection and use of the PICO system (OR, 0.15, p<0.036).

Fleming (2018) reported the results of a retrospective, non-randomized controlled study involving 151 subjects who underwent peripheral vascular surgery and were treated with either PICO-based NPWT (n=73) or standard care (n=78) in the postoperative period. The overall complication rate was significantly lower in the PICO group (6 vs. 15, p=0.042). However, no statistically significant differences between groups were reported with regard to infections (p=0.249), seroma (p=0.069), hematoma, (p=0.531) or dehiscence (p=0.735). Additionally, no significant differences between groups were noted with regard to MRSA infection, readmission rate (p=0.281), or length of stay for readmissions (p=0.465). Total time to full resolution of wound complications was half as long in the PICO group vs. controls (52 days vs. 96 days, p=0.015). This study used a retrospective, unblinded, non-random methodology. Data from more rigorously designed studies would be more helpful in understanding the safety and efficacy of the PICO device.

Galiano (2018) reported the results of an RCT involving 178 subjects undergoing bilateral reduction mammoplasty. In each subject the right and left breast was assigned to treatment with either the PICO system (n=113) or standard care (n=123). The authors reported significantly fewer healing complications in the PICO group (56.8% vs. 61.8%, p=0.004). A sensitivity analysis looking at the treatment effect indicated a 5% absolute reduction, or 10 fewer subjects experiencing a wound complication within 21 days with the PICO system (p=0.033). Within 21 days of surgery a total of 16.2% of PICO group subjects (n=32) experienced wound dehiscence vs. 26.4% (n=52) in the control group (p<0.001). Surgical site infections occurred in 2.0% (n=2) of PICO group subjects vs. 3.0% (n=6) of control subjects within 21 days of surgery (p=0.532).

Another study evaluated use of the V.A.C.Via device in the treatment of 33 subjects who had received 41 graft procedures with either dermal regeneration templates (DRT) and/or skin grafts (Gabriel, 2013). The collected data was compared to a historical control group of 25 subjects with 28 grafts managed with traditional NPWT devices. The average length of inpatient hospital stay was 0.0 days for the V.A.C.Via group and 6.0 days for the control group (p<0.0001). The average duration of treatment was 5.6 days for the V.A.C.Via group and 7.0 days for the control (p<0.0001). The authors concluded that preliminary data suggest that, compared to traditional NPWT, off-the-shelf SP (single patient use) NPWT (V.A.C.Via) may reduce hospital length of stay. The results of these small studies are promising and indicate that the use of these portable and disposable NPWT devices may provide some benefits above the use of standard, rental NPWT device. Additional evidence from larger, randomized comparative trials will be needed to establish an outcome benefit.

Strugala and Martin (2017) reported the results of a meta-analysis involving 1863 subjects with closed surgical site wounds from 16 studies involving the PICO single-use NPWT system. Non-full text, published data such as study abstracts and PhD thesis were included, and there were no restrictions on study type or size. The results involving data from 10 RCTs indicated a significant reduction in infection rates from 9.7% to 4.8% with NPWT intervention (51%; relative reduction, 0.49; p<0.0001). Data from 6 observational studies likewise indicated a significant reduction in infection rates from 22.5% to 7.4% (58%; relative reduction, 0.32; p<0.0001). The combined data was consistent with these findings, with reduction in infection rates from 12.5% to 5.2% (58%; relative reduction, 0.43; p<0.0001). Based on data from 6 studies involving 1068 subjects, there was also a significant reduction in dehiscence from 17.4% to 12.8% with NPWT (26%; relative reduction, 0.71, p<0.01).

Curran (2019) reported a study addressing the use of the Prevena Incision Management System for the treatment of post-surgical closed incisions following high-risk colorectal surgeries. In this study, 77 subjects were treated with NPWT with the Prevena system and 238 subjects underwent standard care. The authors reported that surgical site infections were more frequent in the standard care group (15% vs. 7%, p=0.05). Regression analysis indicated that NPWT was associated with decreased infection rates (OR, 0.27).

Flynn and others (2019) describe a similar study involving 188 subjects following high-risk laparotomy procedures. In this study, 96 subjects were treated with the PICO system and 92 with standard care. Unlike the Curran study, no significant differences in infection rates were reported (13 vs. 14 infections, p=0.73). The authors also reported no significant difference between groups with regard to other surgical site complications (11 vs. 20, p=0.06). The investigators concluded that their findings do not support the use of the PICO system following uncomplicated laparotomy incisions.

Use of the PICO system was reported for prophylactic treatment of cesarean section wounds in 876 obese subjects in an RCT that assigned subjects to treatment with either the PICO device (n=432) or standard care (n=444)

(Hyldig, 2019). Surgical site infections were reported in 20 (4.6%) PICO subjects vs. 41 (9.2%) standard care subjects (Relative Risk [RR], 0.50, p=0.007). The effect remained statistically significant when adjusted for BMI and other potential risk factors. No significant differences were noted with regard to the number of deep surgical site infections requiring surgery (1.9% vs. 2.0%, p=not reported) or the incidence of wound dehiscence (15.1% vs. 16.6, p=0.66). They concluded that prophylactic use of incisional NPWT reduced the risk of surgical site infection in obese women receiving caesarean section procedures.

Keeney (2019) reported the results of an RCT involving 398 subjects undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA). A total of 185 subjects received treatment with PICO NPWT (57 THA and 128 TKA), and 213 received standard care (50 THA and 163 TKA). TKA subjects receiving NPWT with a body mass index > 35 kg/m^2 treated with PICO had fewer complications (1.3% vs 21.6%, p<0.01) and fewer dressing-related concerns (1.3% vs 10.8%, p=0.02) vs. the standard care group subjects. No significant differences in late superficial or deep infection rates were reported (4.0% vs 3.4%, p=0.8). The authors concluded that PICO NPWT may have a targeted benefit for subjects with a body mass index > 35 kg/m^2 undergoing TKA.

Kirsner (2019) reported the results of an RCT of 161 subjects (101 with VLUs, 60 with diabetic leg ulcers [DLUs]) treated with either PICO or standard NPWT. Only 115 subjects (71.4%) completed follow-up (64 PICO subjects and 51 standard subjects). The primary endpoint, wound area reduction, was reported to have a significantly high rate of reduction in favor of PICO group (p=0.003) for the per-protocol population as well as in the intent-to-treat population (p<0.001). PICO subjects were reported to have significantly better results with regard to wound depth (p=0.018) and wound volume (p=0.013). PICO subjects were also reported to have faster wound closure (p=0.019) in the intent-to-treat population. Wound closure occurred in 45% of PICO subjects vs. 22.2% of standard NPWT subjects (p=0.002). The median estimate of the time to wound closure was 77 days for the PICO group, while no estimate could be provided for the standard NPWT group due to the low number of subjects achieving wound closure. The authors concluded that the use of the PICO system met non-inferiority and achieved statistical superiority vs. standard NPWT in terms of wound healing over the treatment period.

The currently available evidence is supportive of the use of portable, battery powered, single use NPWT devices. Multiple reasonably designed and conducted trials investigating the use of these devices have demonstrated a significant benefit with regard to decreased infection and complication rates when compared to standard care.

Non-Electrically Powered Vacuum Assisted Wound Therapy Device

A non-electrically powered vacuum assisted wound therapy device (SNaP Wound Care Device) has been approved by the U.S. Food and Drug Administration (FDA) for market. This device utilizes specialized springs to create the vacuum needed for negative pressure wound therapy. At this time, the available data addressing this type of non-electrically powered vacuum assisted wound therapy is limited. One small study was a retrospective case-control study with 36 subjects in the "non-electrically powered" vacuum treated group compared to a group of 42 subjects who received a variety of other wound therapies (Lerman, 2010). A high drop-out rate was observed with only 21 of the 36 individuals enrolled in the experimental group completing the study. All subjects had either neuropathic or venous stasis ulcers. The authors reported a significantly better improvement in wound size, healing progression, and healing time in the non-electrically powered vacuum assisted wound therapy group compared to the control subjects. This study lacked both randomization of the treatment groups and blinding. A second study was a small case series of 12 subjects with neuropathic or venous stasis ulcers (Fong, 2010). Only 6 of 12 (50%) subjects completed the study. However, complete healing at 4 weeks in 5 of these 6 subjects was reported. The

small sample size, lack of control group, and significant loss to follow-up all hinder the generalizability of these results.

In March 2011, Armstrong and others published the interim results of a small RCT suggesting non-inferiority to standard powered NPWT for the treatment of lower extremity diabetic or venous stasis ulcers. This report included only 33 subjects completing the study to date (n=18 SNaP and n=15 standard powered VAC). In addition to its small size, there are other concerns with this data, including significant differences between the two groups in terms of wound size and age prior to treatment. Initial wound size in the standard VAC group was 8.8 cm^2 and 4.3 cm^2 in the SNaP group. Age of wound was 14 months in the VAC group and 8.3 months in the SNaP group. However, after a covariate analysis of this data, the authors stated that the adjusted results indicated that SNaP subjects continued to demonstrate non-inferiority to the VAC group at 4, 12, and 16 weeks (p=0.033, p=0.042, and p=0.032, respectively).

In May 2012, the final results of this study were published (Armstrong, 2012). The final study enrolled 132 subjects. The authors describe how 17 subjects were dropped from the study. However, another 32 subjects were lost to follow-up and no explanation is provided for their absence. The distribution of these subjects was evenly distributed between the SNaP and VAC groups. To maintain data integrity, these 32 subjects were included in the final analysis using their last observation carried forward to impute missing data points. A total of 83 subjects completed the study by either achieving complete healing or the 16-week therapy period (n=41 in the SNaP group, n=42 in the standard powered VAC group). While subjects and treating medical staff were not blinded to treatment group assignment, evaluation of the primary outcome of wound healing as measured by Visitrak data tracings was conducted in a blinded fashion. The baseline wound size in the VAC group was reported to be much larger than that in the SNaP group, with the majority of wounds greater than 20 cm^2 assigned to the VAC group (n=2 in Snap group, and n=8 in the VAC group). However, the authors report that a nonparametric analysis of covariance supported the non-inferiority of SNaP at all time points with regard to this variable. In an ad-hoc analysis including only subjects with wounds less than 20 cm^2, the authors reported no significant differences in wound size between groups (p=0.06), and that SNaP was non-inferior to the VAC group at the 4, 6, 12 and 16 week time points (p=0.00042, p=0.0099, p=0.0047 and p=0.0036, respectively). Furthermore, no significant difference in wounds healed over time were found in this subgroup (p=0.9365). Although some data is provided addressing adverse events and infections, no comparative statistics are provided for evaluation. Overall, this industry-sponsored study provides some insight into the comparative efficacy of the SNaP and conventional NPWT devices. Further data from larger RCTs comparing the clinical outcomes of wounds treated with the SNaP device, conventional NPWT devices, and standard wound care would be useful.

Marston and others (2015) published the results of a randomized controlled trial involving 40 subjects with refractory venous leg ulcers (VLUs) assigned to treatment with either the SNaP device (n=19) or a standard electrically powered NPWT device (V.A.C®; n=21). At baseline, there were significant differences between the two groups with regard to wound size, with the SNaP group having a mean initial wound size of 4.95 ± 4.49 cm^2 vs. 11.06 ± 12.12 cm^2 for the V.A.C. group. No significant differences were reported with regard to time to wound closure, with or without initial wound sizes taken into account (p=0.35 and p=0.47, respectively). When looking at the endpoint of subjects achieving 50% wound closure, the data indicate that at 30 days, the SNaP group had significantly better healing compared to the V.A.C. group (52.63% vs. 23.8%). Furthermore, when looking at Visitrak tracings of wound size over the course of the study, SNaP-treated subjects had a significantly greater percent of wound healing through 16 weeks (p=0.0005). Additional analysis addressing differences in baseline

wound size indicated that wound size significantly impacted wound size reduction results at 8 and 12 weeks, but not at 16 weeks. These results are promising, and further investigation in larger studies is warranted.

Authoritative Organization Recommendations

In 2016 the Society for Vascular Surgery, the American Podiatric Medical Association, and the Society for Vascular Medicine released joint recommendations related to the management of diabetic foot wounds (Hingorani, 2016). In this document, they provide the following recommendation: "We suggest the use of negative pressure wound therapy 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)."

Background/Overview

The management and treatment of chronic wounds, including pressure ulcers, remain a challenge. Most chronic wounds will heal only if the underlying cause, i.e., venous stasis, pressure, infection, etc., is addressed. In addition, cleaning the wound to remove non-viable tissue, microorganisms and foreign bodies is essential to create the optimal conditions for either re-epithelialization or preparation for wound closure with skin grafts or flaps. Therefore, debridement, irrigation, whirlpool treatments and wet to dry dressings are common components of chronic wound care.

Vacuum assisted wound therapy is used as adjunct to the basic principles of wound care described above. This technique involves applying initial continuous and subsequent intermittent topical negative pressure to an entire wound. The action removes excess fluid from the interstitial space of the wound, enhancing vascular perfusion through vessels compressed by the excess fluid pressure. Additionally, it is believed that removal of excess fluid removes an accumulation of healing-inhibitory factors. Finally, mechanical stretching results in deformation of cellular bridges, which increases cellular proliferation, protein synthesis, and granulation tissue. The net result is accelerated wound closure by re-epithelialization or preparation for wound closure with suturing, skin grafts or flaps (delayed primary intention).

The currently available vacuum assisted wound therapy devices all have some combination of attributes which are used to differentiate them from each other. These attributes include being stationary vs. portable, being operated electrically vs. mechanically, and being reusable or disposable. Stationary devices are usually large and plug into an electrical socket for power. They are intended to be used either in the hospital or some other location where the individual being treated is not very mobile. Newly available portable devices are much lighter and are intended for the treatment of less severely ill individuals who are mobile. Some devices may operate electrically and others via mechanical mechanism (for example, being spring loaded) to create the necessary vacuum for treatment. The vast majority of devices available currently are electrically operated. Finally, there are reusable vs. disposable devices. The available stationary devices are all reusable and used in conjunction with disposable items like bandages and tubing. The disposable devices are usually entirely disposable, and no portion of the devices is reused or saved.

Definitions

Dehisced wounds: A condition where a wound has a premature opening or splitting along natural or surgical suture lines due to improper healing.

Eschar: A dry scab that forms on skin that has been burned or exposed to corrosive agents.

Group 2 or 3 support surfaces: Two groups within the three classifications of specialized pressure reducing bed types available as a preventive measure for bedsores. The classification system is as follows:

- Group 1 - Pressure reducing mattress overlays. These overlays may be filled with air, water, foam or gel and are intended for placement over a standard mattress
- Group 2 - Special mattresses alone or fully integrated into a bed. These mattresses may be filled with air, water, foam or gel and are intended as a replacement for a standard mattress
- Group 3 - Air Fluidized Beds. These are devices that employ the circulation of filtered air through silicone coated ceramic beads that create the characteristics of fluid, creating a sensation of floating

Mediastinitis: A condition characterized by inflammation of the cavity that holds the heart and other organs.

Neuropathic ulcer: An ulcer resulting from the loss of sensation (i.e., pain, touch, stretch) as well as protective reflexes, due to loss of nerve supply to a body part.

Post sternotomy: The period of time immediately following any surgery where the sternum or breastbone is opened to gain access to the chest cavity.

Pressure ulcer (National Pressure Injury Advisory Panel, 2019): A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Pressure ulcer stages:

Pressure Injury:
A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin
Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis
Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to

describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARSI), or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Injury: Full-thickness skin loss
Full-thickness loss of skin, in which adipose (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 4 Pressure Injury: Full-thickness skin and tissue loss
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: Obscured full-thickness skin and tissue loss
Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on an ischemic limb or the heel(s) should not be removed.

Deep Tissue Pressure Injury:
Persistent non-blanchable deep red, maroon or purple discoloration. Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

Medical Device Related Pressure Injury:
This describes an etiology. Medical device related pressure injuries result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.

Mucosal Membrane Pressure Injury:
Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these injuries cannot be staged.

Vacuum assisted wound therapy: A type of medical therapy that involves the use of suction (negative pressure) underneath airtight wound dressings to promote the healing of open wounds that have resisted previous treatments.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

97605	Negative pressure wound therapy (eg, 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 (eg, 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, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, 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 [when specified as utilizing a battery-powered device]
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters [when specified as utilizing a battery-powered device]

HCPCS

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 [when specified as a battery-powered disposable device]
E2402	Negative pressure wound therapy electrical pump, stationary or portable

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met for continuation of therapy.

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above when criteria are not met or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

When services are also Investigational and Not Medically Necessary:

CPT

97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, 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 [when specified as utilizing a manual device]
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters [when specified as utilizing a manual device]

HCPCS

A9272	Wound suction, disposable, includes dressing, all accessories and components, any type each [when specified as a manual device]

ICD-10 Diagnosis

All diagnoses

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Index

InfoV.A.C.® Therapy System
Invia Liberty Wound Therapy
Invia Vario 18 c/i Wound Therapy
Mini V.A.C.®
MyNeWT Negative Pressure Wound System
Neo-Gen One
NPD 1000 Negative Pressure Wound Therapy System
Nexa Negative Pressure Wound Therapy System
PICO Single Use Negative Pressure Wound Therapy System
Prevena™ Incision Management System
Prodigy™ NPWT System (PMS-800 and PMS-800V)
PRO-I™
PRO-II™
PRO-III™
RENASYS EZ™
RENASYS GO™
SNaP Wound Care Device
SVEDMAN®
SVED® Wound Treatment Systems
UNO Negative Pressure Wound Therapy System
V.A.C.
V.A.C. ATS®
V.A.C. Freedom®
VAC Simplicity™
V.A.C.Ulta™
V.A.C.Via Negative Pressure Wound Therapy System
VAWC Device
Vacuum Assisted Wound Closure System
Venturi™ Negative Pressure Wound Therapy
Versatile 1™
VISTA Negative Pressure Wound Therapy

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	05/14/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Deleted INV and NMN statement addressing battery powered devices. Updated Rationale, Coding and References sections.
Reviewed	02/20/2020	MPTAC review. Updated Rationale and References sections.
Reviewed	03/21/2019	MPTAC review. Updated Rationale and References sections.

Revised	03/22/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Removed age criteria from MN section. Updated Rationale and References sections.
Revised	08/03/2017	MPTAC review. Minor typographical revisions made to the MN statement. Updated References section.
Reviewed	08/04/2016	MPTAC review. Updated formatting in Position Statement section. Updated Definitions and Reference sections. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review. Revised position statement regarding absolute contraindications to vacuum assisted wound therapy. Updated Reference section.
Reviewed	05/07/2015	MPTAC review. Updated Rationale and Reference sections.
	01/01/2015	Updated Coding section with 01/01/2015 CPT and HCPCS changes; removed G0456, G0457 deleted 12/31/2014.
Reviewed	05/15/2014	MPTAC review. Added the use battery-powered single use (disposable) vacuum assisted wound therapy devices to the investigational and not medically necessary section. Updated Coding, Reference and Index sections.
	01/01/2014	Updated Coding section with 01/01/2014 HCPCS changes.
Reviewed	05/09/2013	MPTAC review. Reference section updated.
	01/01/2013	Updated Coding section with 01/01/2013 HCPCS changes.
Revised	05/10/2012	MPTAC review. Revised the medically necessary criteria regarding age limitations. Deletion of medically necessary criteria regarding a wound care program being "considered and ruled out". Created new medically necessary statement regarding continuation of therapy and deleted related language from investigational and not medically necessary section. Created new not medically necessary statement regarding contraindications for vacuum assisted wound therapy. Updated Description, Rationale and Reference sections.
	01/01/2012	Updated Coding section with 01/01/2012 HCPCS changes.
Revised	05/19/2011	Medical Policy & Technology Assessment Committee (MPTAC) review. Added 13 years of age and older to Medically Necessary criteria. Updated Rationale, and Reference sections.
Revised	02/17/2011	MPTAC review. Added clarification regarding "electrically powered" devices to position statement. Added the use of non-electrically powered devices as investigational and not medically necessary. Updated Rationale, Background, Coding, Reference, definitions and Index sections.
Revised	08/19/2010	MPTAC review. Added additional criteria to the medically necessary section. Updated Rationale, Reference and Index sections.
Reviewed	08/27/2009	MPTAC review. Updated Reference and Index sections.
Reviewed	08/28/2008	MPTAC review.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	08/23/2007	MPTAC review. Updated the definition of pressure ulcer and the stages of pressure to comply with new guidelines from the National Pressure Ulcer Advisory Panel. Updated references. Coding updated; removed HCPCS A6551 deleted 12/31/2005.
Reviewed	09/14/2006	MPTAC review. References updated.

Reviewed	06/08/2006	MPTAC review. References updated.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes.
	11/22/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	07/28/2004	DME.00009	Negative Pressure Wound Therapy in the Home Setting
WellPoint Health Networks, Inc.	09/23/2004	9.01.04	Vacuum-Assisted Wound Closure