Corporate Medical Policy
Negative Pressure Wound Therapy

Description of Procedure or Service

Negative Pressure Wound Therapy (NPWT) is the application of sub atmospheric pressure to the surface of a chronic or stable wound. This type of wound therapy provides a moist wound bed while removing wound fluid. NPWT creates mechanical forces that draw the wound edges together, induce cell proliferation and cell migration to the wound as well as angiogenesis (Argenta & Morykwas, 1997).

NPWT comprises the application of a foam or gauze type dressing with an adhesive film and connected via tubing to a vacuum pump. Continuous or intermittent controlled negative pressure measuring from 5 to 125 mmHg is applied across the wound. Wound effluent is collected into a disposable canister. Dressing changes are typically performed every 48 to 72 hours during NPWT and no less than 3 times per week for most models; however, some models are designed to stay in place for 7 days. Infected wounds may require more frequent dressing changes (Han & Ceilley, 2017), (KCI, 2014).

Benefit Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member’s Benefit Booklet for availability of benefits.

Preauthorization is required for negative pressure wound therapy provided in an outpatient setting.

Policy Statement

GEHA will provide coverage for negative wound pressure therapy when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated.

When Topical Negative Pressure Therapy for Wounds is covered:

1. Initiation of a Powered Negative Pressure Wound Therapy (NPWT):
   a. An initial 2-week therapeutic trial using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling factors such as diabetes, nutrition, relief of pressure, etc., may be considered medically necessary in the following indications:
      i. Chronic (> 90 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care when:
         1. High-volume drainage interferes with healing; and/or
         2. Standard dressings cannot be maintained due to anatomic factors.
         3. The individual has been on an appropriate turning and repositioning regimen.
4. The individual has used an appropriate pressure relief device (e.g., low air loss bed, alternating pressure mattress) for pressure ulcers on the posterior trunk or pelvis.

5. The individual's moisture and incontinence has been appropriately addressed.

ii. Non-healing wounds in patients with underlying clinical conditions which are known to negatively impact wound healing. Wound must have failed to heal despite optimal wound care for at least 30 days. Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the negative pressure wound therapy.

1. For neuropathic (for example, diabetic) ulcers:
   a. The beneficiary has been on a comprehensive diabetic management program and
   b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities

2. For venous insufficiency ulcers:
   a. Compression bandages and/or garments have been consistently applied, and
   b. Leg elevation and ambulation have been encouraged

iii. Traumatic or surgical wounds with:

   1. Failure of immediate or delayed primary closure not related to infection; AND
   2. Exposed bone, cartilage, tendon, or foreign material within the wound; AND
   3. No contraindications to negative pressure wound therapy (see Policy Guidelines).

iv. Split thickness graft wounds for the following indications:
   1. Remove excessive wound drainage
   2. Secure graft bed

2. **Continuation of a Powered NPWT:**

   a. Continuation of the powered NPWT system, as part of a comprehensive wound care program, may be considered medically necessary following an initial 2-week therapeutic trial or a subsequent treatment period, if the treatment has resulted in documented objective improvements in the wound. Objective improvements in the wound should include the development and presence of healthy granulation tissue, progressive wound...
contracture and decreasing depth, and/or the commencement of epithelial spread from the wound margins.

b. The overall volume of the wound (width X length X depth) is reduced.

**When Topical Negative Pressure Therapy for Wounds is not covered:**

1. Continuation of the powered NPWT system is considered **not medically necessary** when any of the following occurs:
   a. The therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound, OR
   b. The wound has developed evidence of wound complications contraindicating continued NPWT, OR
   c. The wound has healed to an extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments.

2. The use of NPWT for pilonidal cystectomy wounds lacks supporting evidenced based support and is considered experimental/investigational

3. NPWT for closed surgical wounds lacks supporting evidenced based support is considered experimental/investigational.

4. Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above are considered **not medically necessary**.

5. Use of non-powered and disposable NPWT systems for the treatment of acute or chronic wounds is considered investigational.

**Physician documentation**

- Detailed history of tried and failed wound treatments chronologically comparable over 4-6 weeks prior to requested therapy, and off-loading status.
- Recent history and physical including physical impairments and activity status, dietary assessment, and care management plan for patients with diabetes or compromised nutrition status.
- Detailed wound bed description and weekly wound measurements that are chronologically comparable over time.
- For wounds with a history or signs/symptoms of infection include consults with specialties including infectious disease, updated lab including: Wound Cultures, Sedimentation Rate, CRP, and plan of care to treat the infection.
- Vascular studies as indicated
- Any other additional information pertinent to the request.

**Policy Guidelines:**

1. **Contraindications:** to the use of NPWT systems include the following conditions as noted by a November 2009 FDA alert:
a. Necrotic tissue with eschar  
b. Untreated osteomyelitis  
c. Nonenteric and unexplored fistulas  
d. Malignancy in the wound  
e. Exposed nerve  
f. Exposed anastomotic site  
g. And exposed organ.

2. NPWT systems should be used with caution in the following:
   a. Active bleeding or at high risk for bleeding and hemorrhage  
   b. Patients on anticoagulants or platelet aggregation inhibitors  
   c. Difficult wound hemostasis  
   d. When placing the dressing in proximity to blood vessels, care should be taken to ensure that all vessels are adequately protected with overlying fascia, tissue or other protective barrier. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels  
   e. Infected wounds  
   f. Osteomyelitis  
   g. Sharp edges in the wounds (i.e., bone fragments)  
   h. Spinal cord injury (stimulation of sympathetic nervous system)  
   i. Enteric fistulas

3. Continuation of healing during use of the NPWT system should be monitored on a frequency not less than every 14 days.

4. Complete healing of a wound would normally be anticipated if all bone, cartilage, tendons, and foreign material were completely covered, healthy granulation were present to within 5 mm of the surface, and the wound edges were reduced to 2 cm in width or diameter.

5. Powered negative pressure therapy systems should be used as part of a comprehensive wound care program that includes attention to other factors that impact wound healing such as diabetes control, nutritional status, relief of pressure, etc.

6. The focus of these policy statements and guidelines is for use of NPWT in the outpatient setting.

7. 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.
Background

Negative pressure wound therapy uses a sponge and sub atmospheric pressure to facilitate healing of a variety of wounds. The therapy increases wound healing by decreasing excessive wound fluid while facilitating granulation tissue formation. This technology is primarily intended for chronic wounds that have not healed when treated with other forms of wound care and for minimizing scarring on acute wounds by promoting healing through granulation tissue formation and re-epithelization. NPWT may be either a primary or secondary line of treatment, depending on the type of wound.

Although there is a lack of strong evidence to support the use of NPWT, there is moderate evidence that demonstrates benefit from its application.

In 2007, Morris et al. 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 (Moues et al., 2007). 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.

In 2011, de Laat et al. conducted a randomized clinical trial to determine the effectiveness and safety of topical negative pressure therapy in patients with difficult to heal wounds. The study end point was 50% reduction in wound volume and a maximum follow up time of 6 weeks. The results indicated almost 2 times faster wound healing than treatment with sodium hypocholorite.

In 2012, Dorafshar et al. conducted a randomized prospective study of 87 patients with acute wounds resulting from trauma, dehiscence or surgery. The trial compared two methods of subatmospheric pressure wound therapy: wall suction applied to a sealed gauze dressing (GSUC) and the vacuum-assisted closure device (VAC). The conclusion indicated that the GSUC was not inferior to the VAC in regards to wound healing but was easier to apply, less expensive and less painful.

Healing chronic wounds can be a burden to healthcare. Studies have shown mild to moderate cost efficiency when comparing VAC negative pressure therapy to standard moist dressing applications (Fonder et al. 2008), (Anthony, H., 2015), (Frykberg & Williams, 2007), (Armstrong et al. 2011).

Johns Hopkins University Evidence-based Practice Center prepared a comprehensive technology assessment for the Agency for Healthcare Research and Quality (AHRQ) on the effectiveness of negative pressure wound therapy (NPWT) on the treatment of chronic wounds in the home care setting (Rhee et al, 2014). The goal of the assessment was to systematically review the efficacy and safety of NPWT for treatment of chronic wounds in the home setting. The authors included studies examining the use of NPWT in patients with chronic wounds, including venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers, and mixed etiology chronic wounds. They retrieved 5,912 citations, and found seven studies which met the criteria for inclusion. Six of the studies compared NPWT devices to other wound care methods. One study compared two different NPWT devices. Ultimately the assessment’s authors were unable to draw any firm conclusions about the efficacy or safety of NPWT for the
treatment of chronic wounds in the home setting due to insufficient evidence. The authors stated "Though NPWT has been used across the wound care spectrum, 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."

In 2017, Panayi et al. performed an evidence based review of negative pressure wound therapy and concluded, NPWT may have proven successful as an adjunctive therapy in a wide variety of wounds. However, the currently available systems are still novel, and the number of high-level clinical studies investigating NPWT is lacking. More RCTs are needed to elucidate the details of NPWT efficacy, particularly in terms of its different indications and modalities. Overall, NPWT continues to hold great promise and with further research on the optimal parameters of its application this management option stands to continue to improve wound healing and patient care.

Studies performed by Schwien et al. (2007) and Osterhoff et al. (2014) indicate that patients receiving negative pressure wound therapy had a decrease in prolonged treatment and hospital readmissions.

Ousey et al. (2014) explored a pilot study to examine the quality of life experienced by patients being treated with negative pressure wound therapy compared to those receiving standard wound care. Patients being treated with the negative pressure wound therapy were found to have more social interaction and a decrease in symptoms related to wound care. Ousey et al. (2014) also examined the use of portable negative pressure wound therapy devices and found that patients reported that it allowed them to be more mobile and able to participate in activities of daily living.

Disposable Non-Powered Mechanical or Single Use Battery-Powered NPWT/VAC: Smaller disposable non-powered or single use battery-powered NPWT devices have been proposed for the treatment of smaller wounds or on closed incisions after surgery to prevent potentially surgical site infections and other wound complications in high-risk patients. These devices are used in the hospital, outpatient and/or home settings (Armstrong et al., 2012), (Hurd, Tureman & Rossington, 2014).

The latest development in NPWT allows clinicians to instill continuously a treatment solution and suspension into the wound. Negative pressure wound therapy combined with timed, cyclical instillation (NPWTi) of topical wound solutions has been recently presented as a new adjunctive modality for treating wounds with signs of infection. Normal saline, antiseptics and antimicrobials all have been proposed in scientific and clinical studies as potentially effective when used with NPWTi for treating heavily infected wounds (Brinkert et al., 2013). In 2016, Gupta et al released a clinical recommendation and practical guide for negative pressure wound therapy with instillation.

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 (2010) presented a case report in which insulin was used as a chemo-therapeutic agent in continuous-instillation NPWT. Scimeca et al described a real-time streaming therapy of a variety of wound chemo-therapeutic agents through NPWT. Doxycycline may prove helpful when delivered in this manner. The clinical value of chemo-therapeutic agents in continuous-instillation NPWT needs to be ascertained in randomized, controlled clinical trials.

**Pressure Ulcers:**
Initial treatment for pressure ulcers is aimed at relieving pressure by positioning the patient frequently and at a fixed interval to relieve pressure over the compromised area. A number of medical devices, classified as static or dynamic, are designed to relieve pressure. Static devices include air, gel, or water-filled containers that reduce the tissue-to-surface contact. Dynamic devices use a power source to fill compartments with air that support the patient’s weight or alternate the pressure on different areas of the body. It is suggested that patients who fail to improve, or who have multiple pressure ulcers, should be considered for a dynamic type device, such as a low air loss bed or air fluidized bed (AAWC, 2010), (ICSI, 2012), (Sullivan & Schoelles, 2013).

Staging of Pressure Ulcers: When evaluating pressure ulcers, a staging system is typically used that measures tissue destruction by classifying wounds according to the tissue layers involved. In 2016, the National Pressure Ulcer Advisory Panel (NPUAP) renamed the term pressure ulcer with pressure injury and redefined the definition of a pressure ulcer and the stages of pressure injury, including the original four stages and updating two stages on deep tissue injury and unstageable pressure injury.

- **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 the heel or ischemic limb should not be softened or 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.

Vig et al. (2011) published evidence based recommendations suggesting NPWT may be used until surgical closure is possible/desirable; NPWT should be consider to achieve closure by secondary intention; NPWT should be used to decrease wound dimensions and NPWT should be used to improve wound bed quality.

Ashby et al. (2012) conducted a trial that examined the use of NPWT in patients with grade III/IV pressure ulcers and found supporting evidence of increased healing in a shorter amount of time.

Dwivedi et al. (2016) studied pressure ulcer management in paraplegic patients using a novel, innovative NPWT device. The results were promising, showing a significantly higher rate of healing and cost-effective wound healing management.

**Diabetic Neuropathic Ulcers**:

The major contributors to the formation of diabetic ulcers include neuropathy, foot deformity, and ischemia. It is estimated that 60–70% of diabetic ulcers are due to neuropathy, 15–20% are due to ischemia, and another 15–20% are due to a combination of both (CDC, 2014). The neuropathy is both sensory and motor and is secondary to persistently elevated glucose levels. Maintaining optimal blood sugar levels is important. The management of diabetic wounds involves local and systemic measures. Treatment options include relief of pressure at the wound site, surgical debridement, control of infection, and arterial reconstruction. It is recommended that treatment should address the possible presence of osteomyelitis, and should employ antibiotics that achieve adequate levels both in the bone and soft tissue (Edmonds & Foster, 2006).

Foot amputations are commonly related to diabetic non-healing ulcers. Armstrong et. al (2005 & 2007) examined the effects of NPWT on patients with partial foot amputations. It was concluded that patients receiving NPWT healed faster and had fewer returns for further same sided foot amputation.

Studies performed examining NPWT on diabetic neuropathic ulcers revealed a higher rate of wound healing, shorter healing time, greater reduction in wound depth and size and fewer amputations. NPWT should be considered for postoperative grade 2 and 3 diabetic feet without ischemia (Blume et al. 2008), (Dalla et al. 2010), (Fife et al. 2008), (Ikura et al. 2014), (Lavery et al. 2007), (Sajid et al. 2015).
In 2016, Game et al. released guidance recommendations on interventions to enhance healing of chronic ulcers of the foot in diabetic patients. The guidelines specifically support the use of negative pressure wound therapy in the treatment of diabetic foot ulcer care.

**Venous Insufficiency Ulcers:**

Venous stasis occurs due to the incompetence of either the superficial or deep venous systems. Chronic venous ulcers are usually due to the incompetence of the deep venous system and are commonly painless. The wound is usually shallow with irregular margins and pigmented surrounding skin. Compression is the gold standard of treatment of venous disease. After arterial disease has been excluded, reversal of the effects of venous hypertension through compression bandages and leg elevation is the recommended therapy (Collins & Seraj, 2010). After such point NPWT should be considered.

The Association for the Advancement of Wound Care (AAWC) (2010) established guidelines for treatment of venous ulcers including consideration for the use of NPWT.

The Society for Vascular Surgery suggests against routine primary use of negative pressure wound therapy for venous leg ulcers (O’Donnell et al., 2014).

Published studies have demonstrated that in a home setting, chronic wounds associated with venous insufficiency showed a higher likelihood of healing compared to those without NPWT (Dumville et al. 2015), (Marston et al., 2015), (Yao et al. 2014).

**Surgical Wounds:**

NPWT has been used to treat and prevent wounds from post-surgical complications. These may include management of infection, debridement, rewiring (post cardiac), closed antibiotic solution irrigation, prevention of wound dehiscence and promotion of wound healing where there is a need for accelerated formation of granulated tissue.

In a study of 49 patients post-operative pilonidal cyst removal, it was shown that the use of NPWT reduced the wound size more rapidly in the first 2 weeks than traditional wound care. However, there was no difference in the complete time for healing and return to daily life activities (Biter, 2014).

Surgical wound healing is often complicated by obesity. A study done by Hyldig et al. (2015) evaluated the reduction of surgical site infections by prophylactic incisional negative pressure wound therapy compared with standard postoperative dressings in obese women giving birth by caesarean section. The primary outcome was surgical site infection requiring antibiotic treatment within the first 30 days after surgery. Secondary outcomes included wound exudate, dehiscence and health-related quality of life. The conclusion was showed prophylactic use of incisional negative pressure wound therapy reduced the risk of surgical site infection in obese women giving birth by caesarean section.

Webster (Cochrane Review, 2019) concluded despite the addition of 25 trials, results consistent with an earlier review found the evidence in support of negative pressure therapy to closed surgical wounds 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, seroma, or if it increases costs.
Masden et al. (2012) evaluated 81 high-risk with multiple comorbidities for infection and dehiscence postoperatively. There is a significant rate of postoperative infection and dehiscence in patients with multiple comorbidities. There was no difference in the incidence of infection or dehiscence between the NPWT and dry dressing group.

In a study done by Heard et al. (2017), it was shown that NPWT used prophylactically in patients with obesity and caesarean section surgical incisions may be a cost-effective treatment due to the decreased rate of surgical infection and dehiscence but further studies were needed.

Other Considerations:

Studies have shown that NPWT can be an effective treatment in the pediatric population. In general, it was well tolerated and minimized the need for the routine and frequent dressing changes required with traditional wound care techniques. The system aided in closure and/or coverage using relatively simple methods without the need for complex microsurgical interventions (Mooney, et al. 2000).

Venous ulcers are characterized by longstanding and recurrent loss of skin integrity. Once occurred, healing is slow and recurrence is high because of inappropriate conditions of the wound bed. This study involves 20 patients with chronic venous ulcers at least 6 weeks of duration treated with negative pressure wound therapy (NPWT). Patients underwent a radical debridement of all devitalized tissues in the first operation. After adequate hemostasis, silver-impregnated polyurethane foam was applied. Once the wounds were determined to be clean and adequate granulation tissue formation was achieved, split-thickness skin grafts were applied. Black polyurethane foam was applied over them. All wounds completely healed without the need for further debridement or regrafting. The mean number of silver-impregnated foam dressing changes prior to grafting was 2.9 (one to eight changes). The mean number of NPWT foam changes was 2.6 after skin grafting (two to five changes). Two patients who did not use conservative treatments for chronic venous insufficiency (CVI) after discharge from the hospital had recurrence of venous ulcers in the follow-up period. Application of NPWT provides quick wound-bed preparation and complete graft take in venous ulcer treatment (Egemen et al., 2012).

Negative pressure wound therapy (NPWT) has become a widely used treatment for acute and chronic wounds. NPWT is indicated for a variety of complex wounds, and some studies validate its use for certain aspects of burn care. Although further research is needed to explore the benefits for burns, NPWT has proven beneficial in its use as a dressing that bolsters skin grafts, promotes integration of bilaminate dermal substitutes, promotes re-epithelialization of skin graft donor sites, and potentially reduces the zone of stasis (Kantak et al., 2017) (FDA, 2006).

Regulatory Status

Food and Drug Administration (FDA): Negative pressure wound therapy (NPWT) devices are regulated by the FDA as class II devices. In 1995, the V.A.C. Therapy System, manufactured by Kinetic Concepts Inc. (KCI), became the first FDA-cleared NPWT device to be made available in the United States. Since then, several other NPWT devices produced by other manufacturers have also secured FDA clearance. Stationary and portable NPWT systems are available, and recently, a system (SNaP Wound Care System; Spiracur Inc.) that employs a constant force spring to maintain negative pressure rather than relying on electric or battery power has been developed.
Safety concerns, particularly those related to home use of NPWT devices, prompted the FDA to issue a preliminary Public Health Notification and Advice for Patients communication in November 2009 and an updated notice in 2011. The purpose of the initial public health notification in 2009 was to alert healthcare providers, patients, and caregivers regarding the risk of death and serious complications, especially bleeding and infection, associated with the use of NPWT systems, and to provide recommendations to reduce the risk. The alert stated that complications are rare but can occur wherever NPWT systems are used.

The updated safety communication issued in 2011 was meant to inform healthcare providers, patients, and caregivers about FDA activities since issuing the 2009 alert; additional death and injury reports received by the FDA; new recommendations regarding patient selection, education, and monitoring; and information about pediatric use. Between publication of the 2009 and 2011 alerts, the FDA received reports of 6 more deaths and 97 more injuries (total between 2007 and 2011 of 12 deaths and 174 injuries). Three of the additional death reports indicated that the patients were receiving NPWT at home or in a nursing home. Also, in more than half of the additional injury reports identifying the location of care, adverse events occurred either at home or in a long-term care facility. Infection was the most commonly reported injury, and bleeding continued to be the most serious adverse event and was reported in 3 of the additional deaths. The contraindications and patient risk factors provided in the 2009 alert remained the same.

The following codes are for reference only and do not determine benefit coverage. Applicable codes may include but are not limited to:

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<th>Code</th>
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<tr>
<td>97605</td>
<td>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</td>
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<tr>
<td>97606</td>
<td>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</td>
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<tr>
<td>A6550</td>
<td>Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories</td>
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<tr>
<td>A7000</td>
<td>Canister, disposable, used with suction pump, each</td>
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<tr>
<td>E2402</td>
<td>Negative pressure wound therapy electrical pump, stationary or portable</td>
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Considered Experimental/Investigational/Unproven:

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<th>Code</th>
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<tr>
<td>97607</td>
<td>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</td>
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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.

Wound suction, disposable, includes dressing, all accessories and components, any type, each

**Scientific References**


**Policy implementation and updates**

Origination November 2019