



Medical Coverage Policy

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Negative Pressure Wound Therapy/Vacuum-Assisted Closure (VAC) for Nonhealing Wounds

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Related Coverage Resources

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Overview

This Coverage Policy addresses the use of negative pressure wound therapy (NPWT)/vacuum-assisted closure (VAC) for a variety of nonhealing wounds. NPWT is intended to be used in hospitals, clinics, long term care and home care settings. These devices have several features that are used to differentiate them from each other, including being portable vs. stationary, if they are operated electrically vs. mechanically, and if they are reusable or disposable.

Coverage Policy

Coverage for Durable Medical Equipment (DME) including negative pressure wound therapy/vacuum-assisted closure devices and accessories varies across plans. Refer to the customer's benefit plan document for coverage details.

If coverage is available for negative pressure wound therapy/vacuum-assisted closure and accessories, the following conditions of coverage apply.

Powered negative pressure wound therapy (NPWT)/vacuum-assisted closure (VAC) (Current Procedural Terminology [CPT] code 97605, 97606) (HCPCS code A6550, E2402) for nonhealing wounds is considered medically necessary when any ONE of the following conditions exists:

- There are complications of a surgically created wound (e.g., dehiscence, poststernotomy disunion with exposed sternal bone, poststernotomy mediastinitis, or postoperative disunion of the abdominal wall).
- There is a traumatic wound (e.g., preoperative flap or graft, exposed bones, tendons, or vessels) and a need for accelerated formation of granulation tissue not achievable by other topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments).
- There is a chronic, nonhealing ulcer with lack of improvement for at least the previous 30 days despite standard wound therapy, including the application of moist topical dressings, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, and weekly evaluations with documentation of wound measurements (i.e., length, width, and depth) in **ONE** of the following clinical situations:
 - Chronic Stage 3 or Stage 4 pressure ulcer:
 - The individual has been on an appropriate turning and repositioning regimen.
 - 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.
 - The individual's moisture and incontinence have been appropriately addressed.
 - Chronic diabetic neuropathic ulcer:
 - The individual has been on a comprehensive diabetic management program.
 - The individual has had appropriate foot care.
 - The individual has been nonweight bearing if appropriate.
 - Chronic venous ulcer:
 - Compression garments/dressings have been consistently applied.
 - Leg elevation and ambulation have been encouraged.

Medically necessary powered NPWT for up to four consecutive months, including any time during which NPWT was applied in an inpatient setting prior to discharge to home or a wound clinic is considered medically necessary. The use of NPWT beyond four months will be considered medically necessary only when medical necessity continues to be met as previously outlined and there is evidence of clear benefit from the NPWT treatment already received.

Up to 15 dressing kits (A6550) and 10 canister sets (A7000) per month are considered medically necessary unless there is documentation of a large volume of drainage (i.e., > 90 ml of exudate per day) or the wound size requires more than one dressing kit for each dressing change.

Powered NPWT/VAC or associated equipment and supplies for nonhealing wounds or ulcers under ANY of the following conditions is considered not medically necessary:

- An appropriate medical professional is not supervising or performing weekly wound measurement and assessment functions as well as the negative pressure wound therapy dressing changes required.
- Wound healing has occurred to the extent that negative pressure wound therapy is no longer necessary.
- The depth of the wound is less than 1 mm, as wounds of this depth cannot accommodate the sponge.
- Uniform granulation tissue has been obtained.
- The individual cannot tolerate the use of NPWT.
- The wound is infected.
- There is no progression of healing of the wound on two successive dressing changes and/or up to 30 days.

Disposable non-powered mechanical (e.g., Smart Negative Pressure [SNaP®] Wound Care Device) NPWT/VAC (CPT codes 97607, 97608, HCPCS code A9272) is considered experimental, investigational or unproven for any indication.

Disposable single use battery-powered (e.g., PICO™ Single Use Negative Pressure Wound Therapy System, Prevena™ Incision Management System, V.A.C. Via™ Negative Pressure Wound Therapy System, MyNeWT Negative Pressure Wound Therapy System, Uno Negative Pressure Wound Therapy System) NPWT/VAC (CPT codes 97607, 97608, HCPCS code A9272) is considered experimental, investigational or unproven for any indication.

General Background

This information on negative pressure wound therapy/vacuum-assisted closure (VAC) for nonhealing wounds has been developed through consideration of medical necessity and generally accepted standards of medical practice, as well as review of medical literature and government approval status.

Chronic wounds, also known as ulcers, are wounds that have not completed the healing process in the expected time frame, usually 30 days, or have proceeded through the healing phase without establishing the expected functional results. These wounds generally do not heal without intervention and are sometimes unresponsive to conventional therapies. Neuropathic diabetic foot ulcers, pressure ulcers, venous leg ulcers, and arterial ulcers are examples of chronic wounds.

While there are numerous treatments that have been proposed to treat chronic wounds, some have not been well-studied and therefore their safety and effectiveness are as yet unproven. Proposed approaches include: ultrasound, laser, electromagnetic therapy (EM), electrical stimulation (ES), hyperbaric oxygen, gene therapy, surgical debridement, surgical revascularization of the affected area, myocutaneous skin flaps or grafting, wet-to-dry dressings, negative pressure wound therapy, vacuum-assisted closure, and the use of certain bioengineered skin substitutes. When clinically appropriate, all of these interventions are used in combination with aggressive medical management of the underlying wound etiology.

Powered Negative Pressure Wound Therapy (NPWT) or Vacuum-Assisted Closure (VAC)

NPWT or VAC is intended to be used in hospitals, clinics, long term care and home care settings. NPWT involves application of a localized vacuum to draw the edges of the wound together and enhance new growth while providing a moist environment conducive to rapid wound healing. Negative pressure is produced in the wound bed by placing a dressing (i.e., open-celled reticulated foam or moistened gauze) in the wound and sealing the dressing to the skin with a transparent adhesive film dressing. A tube embedded in the dressing connects to a vacuum pump to produce subatmospheric pressure and drain off wound exudate. The vacuum pump provides either continuous or intermittent negative pressure, adjusted for the type of wound. Pressure is applied in the range of 5 to 125 mmHg (adjustable to higher pressures, depending on the particular device used). Manufacturers recommend changing the dressing at 48 hours, then two to three times per week as indicated.

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.

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 (Dohmen, et al., 2014; Hudson, et al., 2013; Fong and Marston, 2012; Lerman, et al., 2010b).

Examples of disposable single-use devices include, but may not be limited to, the following:

The Smart Negative Pressure (SNaP®) Wound Care Device (Spiracur, Inc., Sunnyvale, CA) includes a disposable mechanical (i.e., spring loaded) cartridge to create a vacuum. The cartridge comes in three different pressures from 75-125 mm Hg. Additionally, the system includes a dressing and a strap with attachment clip to attach to the cartridge to the body. It has been proposed that both the traditional electrically powered and

disposable, mechanical powered devices achieve the same air density reduction (negative pressure) (Fong and Marston, 2012).

The pocket-sized disposable PICO™ Single Use Negative Pressure Wound Therapy System (Smith and Nephew, St Petersburg, FL) has an 80 mm Hg pump, two dressing kits and two batteries. This self-contained system is designed to stop working after seven days. It can be used in the hospital and home setting (Hudson, et al., 2013). Substantially equivalent disposable NPWT Systems are the MyNeWT System (Stortford Medical LLC, West Windsor, New Jersey) and the Uno Negative Pressure Wound Therapy System (Genadyne Biotechnologies, Inc., Hicksville, NY).

The Prevena™ Incision Management System is a battery-powered, disposable (single-patient use) negative pressure unit pre-set for continuous NPWT. The batteries are pre-installed with a 192-hour life cycle (8 days). It includes the Prevena Incision Dressing and the Prevena Therapy Canister.

The V.A.C. Via™ Therapy System (KCI, San Antonio, TX) is a portable battery-operated, single patient use, disposable device that can be used for up to seven days. It includes a canister, alarm, tubing, dressing and can provide negative pressure at 75 or 125 mm Hg (Gabriel, et al., 2013).

Chronic Wound Types

Chronic ulcers of the skin include pressure ulcers, arterial ulcers, venous stasis ulcers and neuropathic diabetic ulcers.

Pressure Ulcers: A pressure ulcer is a result of pathologic changes in blood supply to the dermal and underlying tissues, usually because of compression of the tissue over a bony prominence. Pressure ulcers generally appear in soft tissue over a bony prominence (Wester, 2018; Thomas, 2016).

Initial treatment for pressure ulcers is aimed at relieving pressure by repositioning 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 (Wester, 2018; Thomas, 2016).

Other treatment measures of pressure ulcers include: treating pain; assessing nutrition and hydration; removing necrotic debris; maintaining a moist wound environment, which is associated with more rapid healing rates compared to dressings that are allowed to dry; encouraging granulation tissue formation and promoting re-epithelialization; and controlling infection (Wester, 2018; Thomas, 2016).

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. In addition to the change in terminology, Arabic numbers replace Roman numerals to identify the stages. Two additional pressure injury definitions: Medical device and Mucosal Membrane Pressure Injury were added.

The updated staging system includes the following definitions:

Pressure Injury: A pressure injury is localized damage to the skin and 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 (MARS), 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 (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

Additional pressure injury definitions:

- 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.

Venous Stasis 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 (Bonilla-Martinez and Kirsner, 2015).

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. 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. Other proposed therapeutic options include recombinant human growth factors, bioengineered skin substitutes, dressings comprised of extracellular matrix protein, and a variety of synthetic dressings (Barbul, 2005).

Complications of Surgically Created Wounds

NPWT has been proposed as an alternative to surgery to treat complications of surgically created wounds (e.g., sternal wound complication following cardiac surgery). NPWT has been used in patients who have complications of surgically created wounds (e.g., dehiscence) or traumatic wounds (e.g., flap or graft) when there is a need for accelerated formation of granulated tissue that cannot be achieved by traditional topical methods (e.g., the patient has a condition or comorbidity that will not allow for healing times achievable with other topical treatments). In addition, vacuum-assisted wound closure has also been utilized as a noninvasive treatment of deep sternal wound infections following cardiac surgery (i.e., poststernotomy mediastinitis) as an alternative to more invasive treatment such as surgery (e.g., secondary closure or secondary closure with vascularized muscle flaps).

Treatment options in postoperative nonhealing wounds include the following:

- management of infection (e.g., antibiotic therapy)
- wound incision and drainage
- debridement
- rewiring (postcardiac surgery)
- closed irrigation (with antibiotic solution)
- packing of wound
- delayed closure

U.S. Food and Drug Administration (FDA)

In February 2011, the FDA issued an FDA Safety Communication: Update on serious complications associated with negative pressure wound systems. The FDA issued the alert to make individuals aware of deaths and serious complications, especially bleeding and infection, associated with the use of Negative Pressure Wound Therapy (NPWT) systems, and to provide recommendations to reduce the risk. Although rare, these complications can occur wherever NPWT systems are used, including acute and long-term healthcare facilities and at home. Since issuing the 2009 *Preliminary Public Health Notification and Advice for Patients*, the FDA received reports of an additional six deaths and 97 injuries, for a total of 12 deaths and 174 injury reports since 2007. Bleeding continues to be the cause of the most serious adverse events, and was reported in 12 patients, including three of the additional death reports (FDA, 2011a).

The safety and effectiveness of NPWT systems in newborns, infants and children has not been established at this time and currently, there are no NPWT systems cleared for use in these populations. The FDA defines a child as greater than 2—12 years of age (FDA, 2011a; FDA, 2004).

The FDA recommends selecting patients for NPWT carefully, after reviewing the most recent device labeling and instructions and that the patient is monitored frequently in an appropriate care setting by a trained practitioner. In determining the frequency of monitoring, consider the patient's condition, including the wound status, wound location and co-morbidities. The FDA recommends numerous patient risk factors/characteristics to consider before NPWT use. The FDA recommends that NPWT is contraindicated for these wound types/conditions:

- necrotic tissue with eschar present
- untreated osteomyelitis
- non-enteric and unexplored fistulas
- malignancy in the wound
- exposed vasculature
- exposed nerves
- exposed anastomotic site
- exposed organs

Patient risk factors/characteristics to consider before NPWT use:

- patients at high risk for bleeding and hemorrhage
- patients on anticoagulants or platelet aggregation inhibitors
- patients with:
 - friable vessels and infected blood vessels
 - vascular anastomosis
 - infected wounds
 - osteomyelitis
 - exposed organs, vessels, nerves, tendons, and ligaments
 - sharp edges in the wound (i.e. bone fragments)
 - spinal cord injury (stimulation of sympathetic nervous system)
 - enteric fistulas
- patients requiring:
 - MRI
 - Hyperbaric chamber
 - Defibrillation
- patient size and weight
- use near vagus nerve (bradycardia)
- circumferential dressing application
- mode of therapy- intermittent versus continuous negative pressure

Powered NPWT Systems: Numerous powered NPWT systems have received Class II clearance by the FDA through the 510(k) process including, but may not be limited to, the following:

- The V.A.C.[®] Therapy™ device (Kinetic Concepts, Inc. [KCI], San Antonio, TX)
- Versatile 1™ Wound Vacuum system (BlueSky Medical, Inc., Vista, CA).

The FDA indications for use for the V.A.C. Therapy device state that: “The V.A.C. System is a powered suction pump system that is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound* healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or alternating suction pressures. *The V.A.C. is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, pressure ulcers, flaps and grafts” (FDA, 2002).

Disposable Non-Powered Mechanical or Single Use Battery-Powered NPWT/VAC: Numerous disposable NPWT systems have received Class II clearance by the FDA through the 510(k) process.

The Smart Negative Pressure (SNaP)[®] Wound Care Device (Spiracur, Inc., Sunnyvale, CA) received Class II clearance by the FDA through the 510(k) process in 2009. The FDA identifies this generic type of device as, “A

non-powered suction apparatus device intended for negative pressure wound therapy is a device that is indicated for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. It is further indicated for management of wounds, burns, flaps and grafts” (FDA, 2009). Multiple labeling changes of the SNaP Wound Care Device have received FDA 510(k) approval.

The FDA granted 510(k) Class II clearance for the PICO™ Single Use Negative Pressure Wound Therapy System (Smith and Nephew, St Petersburg, FL) on December 15, 2011. The device description states that PICO Single Use Negative Pressure Wound Therapy System is a small, lightweight, portable suction device consisting of a electric motor driven, twin diaphragm, vacuum pump connected to a super-absorbent, gentle adhesive dressing. The pump is supplied non-sterile and single use, the dressing and secondary fixations strips are supplied sterile and single use. The dressing is applied to the wound and secondary fixation strips are placed over the outside edges to help hold the dressing in place. When the suction pump is turned on, air is pulled out of the dressing creating negative pressure and drawing excess fluid from the wound into the dressing. The pump is battery operated and is supplied with two AA lithium batteries which provide up to 168 hours (7 days) of battery life depending upon leak rate. The batteries can be replaced if required. The pump is designed to stop working after 168 hours (7 days) of use and will not re-start after this time, even with new batteries.

The PICO NPWT System was cleared as substantially equivalent to predicate devices Renasys Go (Smith & Nephew), NPD 1000 NPWT System (Kalypto Medical, Hastings, MN), and Prevena™ Incision Management System (KCI, San Antonio, TX). The intended use, indications and instructions for use for the subject and predicate devices are similar. According to the 510(k) clearance document, “the PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. The PICO (single-use NPWT) System is suitable for use in both a hospital and homecare setting. Examples of appropriate wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts, closed surgical incisions” (FDA, 2011b). The FDA granted 510(k) Class II clearance for the PICO 7Y Single Use Negative Pressure Wound Therapy Wound System on January 18, 2019. The PICO 7Y Single Use Negative Pressure Wound Therapy System is substantially equivalent to predicate device for the intended use (FDA, 2019).

The Prevena™ Incision Management System (KCI, San Antonio, TX) received 510(k) clearance on June 11, 2010. The device description states The Prevena Incision Management System consists of the following components: a single use, sterile dressing that is applied in a simple peel and place process; negative pressure is provided to the dressing via a negative pressure therapy unit and wound fluids are collected in a sterile, disposable canister. The indications for use state that the Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy. The predicate device was KCI’s Acti V.A.C. (vacuum assisted closure) Therapy System (FDA, 2010a). The customizable dressing was cleared for marketing in October 2012 and was designated as a combination product in March 2014.

The FDA granted 510(k) Class II clearance for the V.A.C. Via™ Negative Pressure Wound Therapy System, (KCI, San Antonio, TX) on March 10, 2010. Equivalence is claimed to the KCI Acti V.A.C.™ Therapy System (KCI, San Antonio, TX). The device description states that the Via NPWT System consists of the following components: A sterile dressing system applied to the wound and connected via tubing to a therapy unit that generates negative pressure at the wound and a sterile, disposable canister that collects wound exudates removed via the negative pressure. The intended use for the device states, “V.A.C. Via™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudates and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as .diabetic, pressure or venous insufficiency), flaps and grafts” (FDA, 2010b).

The FDA granted 510(k) Class II clearance for the MyNeWT Negative Pressure Wound Therapy System (Stortford Medical LLC, West Windsor, New Jersey) on February 8, 2017. The MyNeWT System is indicated for patients who would benefit from negative pressure wound therapy as it may promote wound healing by removing low to moderate levels (<37.5 ml/day) of exudate and infectious materials. The substantial equivalent device is the PICO system (FDA, 2017a).

The FDA granted 510(k) Class II clearance for the Uno Negative Pressure Wound Therapy System (Genadyne Biotechnologies, Inc., Hicksville, NY) on April 6, 2017. The UNO System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of low to moderate exudates and infectious material. The substantial equivalent device is the PICO system (FDA, 2017b).

Literature Review Powered Negative Pressure Wound Therapy (NPWT) or Vacuum-Assisted Closure (VAC)

The evidence supporting the use of powered NPWT in the treatment of chronic nonhealing wounds exists primarily in the form of nonrandomized, controlled trials; prospective and retrospective large and small case series; single center studies; and single case studies. Numerous systematic reviews have noted the lack of quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. Despite a lack of robust evidence to support its use, NPWT has been shown to be safe and effective for a variety of wound types and has become the accepted standard for a subgroup of patients who have failed a comprehensive, conventional wound therapy program that includes all reasonable, well-established alternative medical treatments. There is also moderate evidence to support the use of this therapy as an alternative to surgery (i.e., secondary closure with or without myocutaneous flap) or in preparation for surgery in patients with poststernotomy mediastinitis. There is insufficient evidence to support the routine use of NPWT (Rhee, et al., 2014; Zhang, et al., 2014; Webster, et al., 2014; Shweiki and Gallagher, 2013; Xie, et al., 2010; Ubbink, et al., 2008; Armstrong, et al., 2007; Llanos, et al., 2006; Stannard, et al., 2006; Andrews, et al., 2006; Armstrong and Lavery, 2005; Moisisidis, et al., 2004; Luckraz, et al., 2003; Song, et al., 2003; Joseph, et al., 2000).

The Centers for Medicare and Medicaid Services (CMS)/ Agency for Healthcare Research and Quality (AHRQ)/ ECRI Institute Evidence-based Practice Center: The CMS partnered with the AHRQ and commissioned a review of NPWT devices. AHRQ contracted with the ECRI Institute Evidence-based Practice Center to perform the review (AHRQ, 2009). A technology assessment report on NPWT prepared for the AHRQ found that “the systematic reviews of NPWT reveal several important points about this technology. First, 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. Second, the other systematic reviews found no studies directly comparing different NPWT devices or components have been published. Direct comparison studies are especially important in determining which dressing approach (foam or gauze) may provide the best potential for wound healing. Third, other systematic reviews concluded that 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 transferred to other wound types. Most wound types have too little high-quality NPWT evidence to judge if NPWT is better than standard care for specific wounds. Studies comparing foam to gauze are needed for each wound type before decisions can be made about which systems or components offer significant therapeutic distinctions.”

Literature Review Disposable Non-Powered Mechanical or Single Use Battery-Powered NPWT/VAC:

The available studies in the peer-reviewed scientific literature addressing disposable non-powered mechanical or single use battery-powered NPWT are generally limited by small sample size and lack of a comparator and therefore conclusions about the safety, efficacy and health outcomes cannot be made at this time. Additionally, many of the studies report that numerous patients were lost to follow-up or dropped out of the studies (Hyldig, et al., 2019; Kirsner, et al., 2019; Singh, et al., 2019; Tanaydin, et al., 2018; Galiano, et al., 2018; Fleming, et al., 2018; Crist, et al., 2017; Lee, et al., 2017; Lo Torto, et al., 2017; Cooper and Bas, 2016; Marston, et al., 2015; Matatov, et al., 2013; Karlakki, et al., 2013; Hudson, et al., 2013; Gabriel, et al., 2013; Fracalvieri, et al., 2012; Armstrong, et al., 2012; Armstrong, et al., 2011; Lerman, et al., 2010a, Lerman, et al., 2010b).

Saunders et al. (2021) conducted a systematic review and meta-analysis to compare the prophylactic use of the PICO single-use negative pressure wound therapy system to conventional dressings in the prevention of surgical-site complications after closed surgical incisions. Twenty-nine studies (n=5614) including 11 randomized controlled trials, 13 observational studies and five conference abstracts met inclusion criteria. The inclusion criteria were studies that enrolled patients with a closed surgical incision and at any risk factor for surgical-site complications. The intervention was the PICO compared to any non-negative-pressure wound therapy (NPWT) dressing. Studies that included patients with an open surgical incision or any non-surgical wound, as well as studies that did not use PICO, were excluded. Data was assessed from orthopedic, colorectal, obstetric, breast, vascular, and cardiovascular specialty procedures. Results showed that surgical site infections were reduced by 63% with PICO compared to conventional dressings, and noted a significant decrease for wound dehiscence, seromas, necrosis, and mean hospital length of stay. Surgical site complications of hematomas, delayed healing, abnormal scarring, and time of healing did not show significant difference between the two groups. Author noted limitations of the analysis included: small patient populations, heterogeneity of reported outcomes, variation in the criteria used to define a patient as high risk, and lack of blinding of patients and clinicians for most studies. Other limitations include the fact that the authors did not report the number of patients per study or the follow-up time of the studies, and conference abstracts were included.

In a multicenter, prospective randomized controlled trial, Kirsner et al. (2019) compared the efficacy and safety of a single-use negative pressure wound therapy (s-NPWT) system versus traditional NPWT (t-NPWT) for the management of lower extremity ulcers, including both venous leg ulcers (VLUs), diabetic foot ulcers (DFUs). The intent to treat (ITT) population was composed of 161 patients (101 with VLUs, 60 with DFUs) and 115 patients completed follow-up in the per protocol population (PP) (64 in the s-NPWT group and 51 in the t-NPWT group). The primary objective was to assess an s-NPWT system versus t-NPWT (different brands) for the percentage change in target wound area over a 12-week period from baseline. Secondary endpoints were the percentage change in the target ulcer depth and volume, time (in days) to achieve complete target ulcer closure, and the proportion of patients that achieved confirmed complete target ulcer closure. The study included adult patients of both genders with either a VLU present for more than four weeks and measuring 2-36 cm² in surface area or a DFU present for more than four weeks and measuring 0.5-10 cm² in surface area and a confirmed adequate arterial supply. Exclusion criteria included suspected or known allergies to the components of the different NPWT systems; pregnancy; participation in other research within 30 days of screening; ulcers deemed by the investigator to be highly exuding; anatomic location not amendable to the creation of an airtight seal; malignancy in the target ulcer; concurrent diagnosis of vasculitis or claudication; current administration of systemic chemotherapy or corticosteroids; previous treatment with NPWT or hyperbaric oxygen within seven days of screening, leukopenia, thrombocytopenia, anemia, two-fold or higher increase in bilirubin levels, three times or higher increase in hepatic enzymes. For individuals with nondiabetic ulceration, exclusion criteria also included: ulcers whose etiology was nonvenous (e.g. sickle-cell anemia, pyoderma gangrenosum, vasculitis), the presence of deep vein thrombosis, the refusal or inability to tolerate compression therapy, exposure of muscle, tendon or bone in the target ulcer, the size of the target ulcer was >15 cm in one linear direction. For individuals with DFU, exclusion criteria also included: diagnosis of active Charcot foot syndrome and the location of the target wound on the toes. The ITT populations attended at least one follow-up post baseline visit. Primary endpoint analyses on wound area reduction was statistically significant reduction in favor of s-NPWT (p=0.003) for the PP population and for the ITT population (p<0.001). Changes in wound depth (p=0.018) and volume (p=0.013) were also better with s-NPWT. Faster wound closure was observed with s-NPWT (p=0.019) in the ITT population. Wound closure occurred in 45% of patients in the s-NPWT group; 22.2% of patients in the t-NPWT group (p=0.002). Median estimate of the time to wound closure was 77 days for s-NPWT. No estimate could be provided for t-NPWT due to the low number of patients achieving wound closure. Device-related AEs were more frequent in the t-NPWT group (41 AEs from 29 patients) than in the s-NPWT group (16 AEs from 12 patients). This study is limited by small sample size.

In a multicenter, comparative, randomized controlled trial the mechanically powered SNaP Wound Care System was compared with the electrically powered VAC Therapy System. Initial enrollment included 132 individuals. Seventeen patients dropped from study before treatment started for unknown reasons leaving 115 individuals available for follow-up data (i.e. 59 SNaP; 56 VAC). The inclusion criteria was for patients aged ≥18 years; lower extremity venous ulcer or diabetic ulcer with a surface area <100 cm² but larger than 1 cm², and <10 cm in widest diameter. Wounds were to have been present for >30 days despite appropriate wound care prior to entry. Adequate blood perfusion defined as either transcutaneous oxygen measurements of the dorsum of the foot >30

mmHg, skin perfusion pressure >30 mmHg, or an ankle/brachial index between 0.7 and 1.2. The wound was required to be in a location amendable to creation of an airtight seal using the provided dressings. Exclusion criteria included active infection (redness, swelling, pain, purulent exudate), untreated osteomyelitis, pregnancy, allergies to wound care products used in the study and etiologies of the wound that included malignancy, burn, collagen vascular disease, sickle cell, vasculopathy, or pyoderma gangrenosum. A diagnosis of active Charcot foot syndrome, wound location on toes or plantar surface of foot, uncontrolled hyperglycemia (glycated hemoglobin [HbA1C] >12%), end-stage renal disease requiring dialysis, active chemotherapy treatment, previous treatment with a NPWT device, growth factors, hyperbaric oxygen, or bioengineered tissue product within 30 days of enrollment. Patients were not enrolled if they exhibited greater than 30% wound surface area reduction in size at one week after the screening visit.

Each subject was randomly assigned (1:1) to treatment with either system in conjunction with appropriate off-loading and compression therapy. Subjects were evaluated on a weekly basis to complete wound closure (defined as complete reepithelialization without drainage) or for up to 16 weeks of therapy. Dressing changes were performed following manufacturer recommended instructions. Wound size and age of the wounds varied between the two groups. The primary outcomes evaluated in this study were percent wound closure at 4, 8, 12, and 16 weeks. To establish noninferiority to traditional NPWT, this study was powered assuming 80% wound closure with an 18.5% standard deviation (derived from previous study wounds treated with the SNaP system) for both groups at 16 weeks using a margin of noninferiority of 12.5%. Primary end point analysis of wound size reduction found that SNaP-treated subjects demonstrated non-inferiority to the VAC treated subjects at 4, 8, 12, and 16 weeks ($p=0.0030$, 0.0130 , 0.0051 , and 0.0044 , respectively). Eighty-three patients ($n=41$ SNaP, $n=42$ VAC) completed the study with either healing or 16 weeks of therapy. Device related adverse events and complications such as infection were similar between treatment groups. The authors reported that wound types that may respond best to each form of wound interface layer during NPWT still need to be defined in additional studies. Additionally, further comparative effectiveness studies specifically designed to assess specific wound etiologies are warranted (Armstrong, et al., 2012).

The interim analysis to the above study compared the mechanically powered SNaP Wound Care System to the traditional electrically powered VAC Therapy System in the treatment of chronic lower extremity wounds. This 12-center randomized controlled trial of patients with noninfected, nonischemic, nonplantar lower extremity wounds enrolled 65 patients. The trial evaluated treatment for up to 16 weeks or till complete closure was achieved. Fifty-three patients ($n=27$ SNaP, $n=26$ VAC) completed at least 4 weeks of therapy. Thirty-three patients ($n=18$ SNaP, $n=15$ VAC) completed the study with either healing or 16 weeks of therapy. At the time of planned interim analysis, no significant differences in the proportion of subjects healed between the two devices evaluated were found. The percent wound size reduction between treatment groups was not significantly different at 4, 8, 12, and 16 weeks, with noninferiority analysis at 4 weeks of treatment reaching ($p=0.019$). Wound size and age of wound differed between the two groups. Initial wound size in the standard VAC group was 8.8 sq cm and 4.3 sq cm in the SNaP group. Age of wound was 14 months in the VAC group and 8.3 months in the SNaP group. The proportion of patients experiencing one or more device-related adverse events was similar between the VAC and SNaP treatment groups (Armstrong, et al., 2011).

In a retrospective study with historical controls Lerman et al. (2010b) compared NPWT using the SNaP device ($n=21$) with wound care protocols that included the use of Apligraf, Regranex and skin grafting ($n=42$) for treatment of lower extremity ulcers. There were a total of 36 subjects enrolled prospectively in the first phase of the study, and 21 subjects completed treatment with the SNaP device. Of the 15 subjects that did not complete the study, seven subjects had complications (e.g., allergic reaction, wound infection) that required premature termination of SNaP treatment. Compared with the matched controls, there was a 47.4 % absolute improvement in the percentage of wounds healed when subjects were treated with the SNaP device as compared with modern dressings over a 4-month period. The study is limited by study design, the multiple modalities used in treatment of the control group, and the large number of dropouts.

In a prospective multicenter study, Hudson et al. (2013) assessed overall functionality and performance of the disposable PICO NPWT system including the ability of the system to manage exudate without a canister, concomitant delivery of NPWT and wound progress towards healing during the treatment phase. The study included 20 individuals. Sixteen had closed surgical wounds, two had traumatic wounds and two received meshed split thickness skin grafts. The mean study duration was 10.7 days (range: 5–14 days) and the mean

dressing wear time per individual patient was 4.6 days (range: 2–11). A total of 55% of the wounds had closed by the end of the 14-day study or earlier, with 40% of wounds progressing to closure. Two wounds were clinically infected and a further wound had clinical signs of infection at recruitment. Two of these wounds were successfully skin grafted during the treatment period. One device-related adverse event observed small blister-like lesions around the wound associated with the removal of adhesive film fixation strips. This study is limited by small sample size and lack of a comparator.

In a retrospective study, Gabriel et al. (2013) evaluated use of the disposable, single-patient-use NPWT system (SP-NPWT) V.A.C. Via™ Therapy over dermal regeneration template (DRT) and/or skin grafts. SP-NPWT was initiated over a DRT and/or skin graft in 33 patients with 41 graft procedures. Endpoints were recorded and compared to a historical control group of 25 patients with 28 grafts bolstered with traditional rental NPWT (V.A.C.). Mean age was less for the SP-NPWT group versus the control and there were significantly more patients with peripheral vascular disease (PVD) in the SP-NPWT group compared with the control (12 versus 0, respectively). A greater number of acute wounds were present in the SP-NPWT group versus the control (26 versus 10, respectively). All other patient demographics and wound characteristics were similar. Mean follow-up time was 6.4 months for the SP-NPWT group and 12.7 months for the control group. Primary endpoint was time to hospital discharge, duration of SP-NPWT and graft take rate were collected and compared to a historical control group of patients who received traditional rental NPWT over dermal regeneration template (DRT) and/or skin grafts. Average length of inpatient hospital stay was 0 days for the SP-NPWT group and six days for the control group. The average duration of SP-NPWT post-DRT or skin graft was 5.6 days and 7.0 days for the control. This study is limited by small sample size, lack of a comparator, and observer bias in estimating graft take. The authors reported that considerably more controlled research is necessary to measure efficacy of SP-NPWT in the adjunctive management of various wound types.

Singh et al. (2019) performed a meta-analysis of 30 studies evaluating single-use NPWT systems for treating closed wounds. Randomized controlled trials and observational studies were assessed across specialties including vascular surgery, cardiothoracic, lower extremity, obstetrics and colorectal/abdominal. Results demonstrated that the Prevena system performed significantly better at reducing the incidence of surgical site infections in comparison to traditional and advanced wound dressings. The reported limitations include heterogeneity of data and lack of high-quality studies for the review.

Scalise et al. (2016) conducted a systematic review to evaluate incisional negative pressure wound therapy (INPWT)'s effect on surgical sites healing by primary intention. The study included the Prevena and Pico systems which have been the focus of a new investigation on possible prophylactic measures to prevent complications via application immediately after surgery in high-risk, clean, closed surgical incisions. A total of six randomized controlled trials, five prospective cohort studies and seven retrospective analyses, were included. The primary outcomes included incidence of complications (infection, dehiscence, seroma, hematoma, skin and fat necrosis, skin and fascial dehiscence or blistering) and other variables influenced by applying INPWT (re-operation and re-hospitalization rates, time to dry wound). The study sample included 1042 incisions on 1003 patients. The majority of the studies in this review evaluated the use of INPWT in orthopedics. The remaining studies included INPWT used post cardiac surgery and for abdominal incisions. The authors reported that the studies showed a decrease in the incidence of infection, sero-hematoma formation and on the re-operation rates when using INPWT. Lower level of evidence was found on dehiscence, decreased in some studies, and was inconsistent to make a conclusion. Because of limited studies, it is difficult to justify strong assertion and recommendation regarding the effect of INPWT on the rate of skin necrosis and blistering and of time until attainment of dry wound. The authors concluded that although INPWT is safe and potentially beneficial, data is insufficient to recommend widespread use of this technology.

Professional Societies/Organizations

The American Society of Plastic Surgeons (ASPS) evidence-based clinical practice guideline for chronic wounds of the lower extremity states, "Although the wound care literature is rife with uncontrolled studies reporting the effectiveness of negative pressure wound therapy, few prospective randomized trials exist. Despite a lack of strong evidence to support its use, negative pressure wound therapy has gained wide acceptance by multiple specialties for a myriad of wounds" (ASPS, 2007).

The American College of Foot and Ankle Surgeons (ACFAS) 2006 diabetic foot disorders clinical practice guideline addresses the treatment of diabetic foot infections. The authors state the primary treatment goal for diabetic foot ulcers is to obtain wound closure as expeditiously as possible. The authors state that along with other dressings, NPWT may be useful to aid in the healing of surgical wounds of the diabetic foot. If the wound fails to show signs of healing, the patient's vascularity, nutritional status, infection control, and wound offloading must be re-evaluated (Frykberg, et al., 2006).

An endorsement for a particular NPWT device was not located in any professional society guideline.

Use Outside of the US

A 2019 NICE Medical Technologies Guidance PICO addressing negative pressure wound dressings for closed surgical wound incisions concluded that PICO negative pressure wound dressings should be considered as an option for closed surgical incisions in people who are at high risk of developing surgical site infections. They are associated with fewer surgical site infections and seromas compared with standard wound dressings. The authors state that the clinical and statistical heterogeneity of the studies as a limitation. There is a wide variation in the risk characteristics of the populations, the definition of surgical site infections, how long the dressing was in place and the length and frequency of follow-up (NICE, 2019).

Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|-----|--|--|-------------------------|
| NCD | | No National Coverage Determination found | |
| LCD | National Government Services, Inc. | Negative Pressure Wound Therapy Pumps (L33821) | 1/1/2020 |
| LCD | First Coast Service Options, Inc. | Wound Care (L37166) | 7/23/2020 |
| LCD | Novitas Solutions, Inc. | Wound Care (L35125) | 7/23/2020 |
| LCD | Wisconsin Physicians Service Insurance Corporation | Wound Care (L37228) | 1/28/2021 |

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|-------------|---|
| 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 |

| HCPCS Codes | Description |
|-------------|--|
| A6550 | Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories |
| A7000 | Canister, disposable, used with suction pump, each |
| E2402 | Negative pressure wound therapy electrical pump, stationary or portable |

Considered Experimental/Investigational/Unproven:

| CPT® Codes | Description |
|------------|--|
| 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 instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters |
| 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 instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters |

| HCPCS Codes | Description |
|-------------|--|
| A9272 | Wound suction, disposable, includes dressing, all accessories and components, any type, each |

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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