Non-Powered Negative Pressure Wound Therapy in the Outpatient Setting

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DESCRIPTION

***Note**: This policy applies to the use of non-powered negative pressure wound therapy (NPWT) systems (mechanical or single use (disposable) battery operated devices) in the outpatient setting.*

The management and treatment of chronic wounds, including decubitus ulcers, is challenging. Most chronic wounds will heal only if the underlying cause (i.e., venous stasis, pressure, infection) is addressed. Also, cleaning the wound to remove nonviable tissue, microorganisms, and foreign bodies is essential to create optimal conditions for either re-epithelialization (i.e., healing by secondary intention) or preparation for wound closure with skin grafts or flaps (i.e., healing by primary

intention). Therefore, debridement, irrigation, whirlpool treatments, and wet-to-dry dressings are common components of chronic wound care.

Negative pressure wound therapy (NPWT) involves the use of a negative pressure or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue and wound healing. The devices may also be used as an adjunct to surgical therapy or as an alternative to surgery. Although the exact mechanisms have not been elucidated, it is hypothesized that negative pressure contributes to wound healing by removing excess interstitial fluid, increasing the vascularity of the wound, reducing edema, and/or creating beneficial mechanical forces that lead to cell growth and expansion.

Negative pressure wound therapy (NPWT) devices are classified as either powered (i.e., requiring an electrical power source) or non-powered (mechanical) or battery operated. Most evidence found in the literature is for electrically powered devices with large canisters (e.g., such as vacuum-assisted devices). Several non-powered negative pressure wound therapy (single use) portable devices have entered the market for use in the outpatient setting. Some non-powered negative pressure wound therapy (single use) portable devices are designed specifically for surgical incisions.

Conventional NPWT using a powered negative pressure wound therapy system can be bulky and intrusive for patients who are ambulatory and active, disposable non-powered negative pressure wound therapy (NPWT) (mechanical) or single use (disposable) non-powered (battery operated) negative pressure wound therapy have been proposed for the treatment of small to medium sized, slow to heal wounds and for the management of surgical incisions. The goal of these devices is to make it easier to use by both the clinicians and patients. Specifically, the device should be one that clinicians can take off the shelf like any other wound care dressing, it is quick and easy to apply, and the patients can wear under their clothes and will not impinge on their normal activities. The idea was to make it practical and cost effective, allowing more patients to benefit from NPWT in the outpatient/home setting. *This policy applies to the use of non-powered negative pressure wound therapy (NPWT) systems (mechanical or single use (disposable) battery operated devices) in the outpatient setting.*

Portable Single Use Negative Pressure Wound Therapy (NPWT) Devices

Clinical Context and Therapy Purpose
The purpose of portable single-use outpatient negative pressure wound therapy (NPWT) devices is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with any small to medium sized, slow to heal wounds and for the management of surgical incisions

Populations
The relevant population of interest is individuals with small to medium sized, slow to heal wounds and for the management of surgical incisional wounds.

Interventions
The therapy being considered is portable single-use outpatient NPWT, which is administered in wound clinics and the home care setting.

Device	Device Indication
AVELLE Negative Pressure Wound Therapy System	The AVELLE negative pressure wound therapy (NPWT) system is designed to produce a continuous negative pressure of 80mmHg (+/- 20 mmHg) across the wound surface through the hydrated Hydrofiber Technology Dressing to the wound bed through 4 layers of AQUACEL Extra Dressing to a depth of 2 cm for over 7 days. It is a battery powered disposable pump with a 30-day lifetime. This NPWT system has a one-way valve that helps maintain continuous pressure after removing the pump from the dressing for up to 1 hour +/- 10 mmHg, therefore, patients can keep the dressing in place by disconnecting the pump to shower. The Hydrofiber Technology: • Balances wound fluid levels through gelling to maintain a moist wound healing environment. • Locks in wound exudate and traps bacteria to help protect peri-wound skin and reduces maceration. • Micro-contours to the wound bed, minimizing dead space where bacteria can grow. The AVELLE NPWT system can be used for low to moderate exuding wound types: • Acute wounds • Chronic wounds • Flaps and grafts • Traumatic wounds • Subacute and dehisced wounds • Surgically closed incisions

ciSNaP Closed Incision System	ciSNaP Closed Incision System (Spiracur, Sunnyvale, CA) is a single use portable, non-powered, disposable negative pressure wound therapy system that is intended for wound management through the removal of small amounts of exudate from surgical incisions that continue to drain following sutured or stapled closure. The ciSNaP Closed Incision System has a sterile cartridge that provides negative pressure therapy which increases blood flow to improve wound healing. There is proprietary spring mechanism that generates consistent, even levels of pressure. A visual indicator displays when cartridge is full or discharged. Silicone wings help to approximate wound edges, reducing potential risk of dehiscence and minimizing tension on staples and sutures which is customizable in length to fit a wide range of incisions. A proprietary hydrocolloid dressing and antimicrobial gauze offer a protective barrier to minimize potential for infection and eliminate the need for dressing changes. A soft strap enables the device to be conveniently worn on the extremity or belt. The use of the ciSNaP Closed Incision System over surgical incisions may result in: • Lowered rate of infection • Reduced risk of dehiscence • Improved cosmesis • Fewer complications and associated costs
extriCARE® 2400 Negative Pressure Wound Therapy System	Is a lightweight, portable, and battery-powered device that works in conjunction with extriCARE's foam or anatomically fitted dressings. The extriCARE® 2400 Pump has the option of either continuous or intermittent vacuum modes allowing the ability to personalize treatment.

Invia Motion Negative Pressure Wound Therapy System	The Invia Motion Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (NPWT) as when used on open wounds it creates 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 exudate and infectious material. When used on closed surgical incisions, the Invia Motion NPWT system is also 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 (NPWT). The Invia Motion NPWT system is appropriate for the following indications: • Acute or subacute wounds • Chronic wounds • Closed surgical incisions • Diabetic/Neuropathic ulcers • Dehisced wounds • Flaps and grafts • Partial thickness burns • Pressure ulcers • Traumatic wounds • Venous insufficiency ulcers Wound dressings are to be applied and changed by healthcare professional only. Routine dressing changes should occur every 48-72 hours and dressing changes for infected wounds should be considered more frequently.

myNeWT Negative Pressure Wound Therapy System	The myNeWT negative pressure wound therapy system is a portable, disposable, single use system for patients who have hard to heal wounds. Therapy is accomplished by the pump delivering a continuous negative pressure to the wound surface (80mm Hg +/- 20 mmHg), which draws exudate into a flexible canister, creating an environment that promotes wound healing via the removal of low to moderate amounts of exudate and infectious material from the wound. This disposable pump is battery operated and driven by a 2AA primary lithium batteries which allows it to deliver therapy for 7 days. A sterile wound interface connects the wound dressing to the flexible canister. The myNeWT system is indicated for patients with the following wound types: • Acute, sub-acute and dehisced wounds • Chronic wounds • Closed incision sites • Diabetic ulcers • Flaps and grafts • Partial thickness burns • Pressure or venous insufficiency ulcers • Traumatic wounds
NPWT PRO to GO	Is indicated for the application of continual or intermittent negative pressure wound therapy to the wound. • Accommodates large wounds • Accommodates small wounds Portable and battery operated. Providers continuous or intermittent pressure.
PICO Single Use Negative Pressure Wound Therapy System, PICO 7, or PICO 7Y Single Use Negative Pressure Wound Therapy System	PICO Single Use Negative Pressure Wound Therapy System 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 levels of exudates and infectious materials. Examples of appropriate wound types include: • Acute wounds • Chronic wounds • Partial thickness burns • Subacute and dehisced wounds • Traumatic wounds • Ulcers (such as diabetic or pressure) • Flaps and graft • Closed surgical incisions to reduce surgical site complications PICO 7Y single use negative pressure wound therapy system (sNPWT) has these additional features: • Provides negative pressure wound therapy (NPWT) to two dressings on the same patient simultaneously from one small portable device. • Large multisite dressing provides improved comfortability compared to standard PICO dressing. • Longer 450mm sortport for ease of dressing connection. • Includes the following same features as PICO 7: quiet pump, integrated belt clip, vacuum leak indicator and new check dressings' indicator. The PICO 7Y delivers and maintains NPWT at 80mmHg (nominal) to two closed sites simultaneously for up to 7 days, depending on exudate levels and the check dressing indicator aims to optimize dressing changes. It is designed for hard -to -seal or awkward anatomical locations with fluid management to help minimize the risk of maceration. In vitro testing demonstrated that once bacteria is within the dressing up to 99.9% of bacteria was locked away from the wound when

	absorbed into a superabsorber via the AIRLOCK technology layer.
Prevena ™ Incision Management System, Provena ™ Plus Duo Incision Management System, or Provena ™ Restor Incision Management System	Prevena Incision Management System is a negative pressure wound therapy (NPWT) device designed specifically for management of closed surgical incisions that continue to drain following sutured or stapled closure. The single use system consists of a negative pressure therapy unit, a canister, and dressing. The therapy unit uses three AA batteries to deliver 125 mm Hg of negative pressure to the incision site and has an eight-day life. Therapy may last for a minimum of two to seven days. The therapy unit has alerts for leaks, low battery, maximum capacity and system errors. There are two dressing options Prevena Peel and Place dressing for incisions fewer than 8 inches and the Prevena Customizable dressing for incisions up to 35 inches or nonlinear. NPWT applies a localized vacuum to draw the edges of the wound together while providing a moist environment conducive to wound healing. Provena Restor Incision Management System expands the amount of time that negative pressure can be applied to a total of 14 days with a dressing change at 7 days. This system is suitable for use with sutured or stapled wounds. Provena Plus Duo Incision Management System was designed for use on two linear incisions up to 13 and 20 cm in length (a 13 and 20 cm dressing or two 20 cm dressings)
RENASYS ™ GO	The RENASYS GO is indicated for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

	Appropriate wound types include: • Chronic • Acute • Traumatic • Sub-acute and dehisced wounds • Ulcers (such as pressure or diabetic) • Partial-thickness burns • Flaps and grafts
SNaP ® Wound Care System	The SNaP System is indicated for the removal of small amounts of exudate from the following types of wounds: • Chronic wounds such as diabetic foot ulcers, venous ulcers, and pressure ulcers • Flaps and grafts • Partial-thickness burns • Subacute and dehisced • Surgically closed incisions • Traumatic/acute It is recommended that the dressing be changed at least two times per week by the patient's healthcare provider. The frequency of the dressing changes will depend on a number of factors (i.e., the level of exudate, bacterial load and rate of granulation tissue).
UNO Negative Pressure Wound Therapy System (UNO Single Patient Disposable Negative Pressure Wound Therapy System)	The UNO single patient disposable negative pressure wound therapy system is battery operated and offers two options of therapy treatment time: • UNO 7 is a 7-day disposable negative pressure wound therapy system that includes 1 canister, 2 dressing kits, 1 carry pouch, and 2 sets of batteries: or • UNO 15 is a 15-day disposable negative pressure wound therapy system that includes 2 canisters, 5 dressing kits, 1 carry pouch, and 5 sets of batteries.

	The UNO single patient disposable negative pressure wound therapy system has two modes of operation: • Continuous at either 125 mmHg or 80 mmHg; or • Variable at either 80 mmHg/30 mmHg or 125 mmHg/30 mmHg. The indications for the UNO single patient disposable negative pressure wound therapy system: • Dehisced wounds • Flaps and grafts • Partial thickness burns • Trauma wounds • Chronic wounds – pressure ulcers, venous ulcers, and diabetic foot ulcers
V.A.C. Via ™ Therapy System	V.A.C. Via Therapy System (KCI, San Antonio, TX) is a portable single patient use negative pressure wound therapy device that offers 7 days of therapy. Provides dynamic pressure control and continuous negative pressure options of 75mmHg or 125mmHg. The system is designed for moderate to lower-severity wounds and provides the same clinical efficacy as current V.A.C. ® therapy products. The V.A.C. Via System creates an environment that promotes healing by 1) maintaining a moist wound healing environment, 2) remove excess wound fluids and infectious material and 3) creating an environment that promotes perfusion and granulation tissue formation. V.A.C. Via Therapy System is indicted for open wound types including chronic, acute, traumatic, subacute, and dehisced wounds, partial thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

	When used on closed surgical incisions, it 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 exudates via the application of negative pressure wound therapy.
XLR8 Plus Negative Pressure Wound Therapy Pump	XLR8 Plus Negative Pressure Wound Therapy Pump is a more powerful pump which easily handles the largest of wounds for extended periods of time, offering continuous and variable pressure setting options, as well as intensity level setting options. FDA approved for both hospital and home care.

Comparators
The following therapies are currently being used to make decisions about the treatment of small to medium sized, slow to heal wounds and for the management of surgical incisional wounds: standard wound care and standard power negative pressure wound therapy (NPWT) (power vacuum assisted).

Outcomes
The general outcomes of interest are symptoms, change in disease status, quality of life (QOL), and treatment related morbidity. Follow-up at weeks to months is of interest for portable single-use outpatient NPWT to monitor relevant outcomes.

Review of Evidence – Diabetic Lower-Extremity Ulcers and Amputation Wounds
PICO is a portable single-use NPWT system that comes with 2 sterile dressings and has a lifespan of 7 to 14 days.

Kirsner et al (2019) published an RCT that allocated 164 patients with venous leg ulcers (n=104) or diabetic foot ulcers (n=60) to treatment with PICO single-use NPWT (s-NPWT; n=80) or traditional, reusable NPWT systems (t-NPWT; n=84). Prior to randomization, patients were excluded if a reduction in target ulcer area ≥30% was achieved with compression or offloading during a 2 week run-in period as a way to exclude 'quick healers'. Three patients in the t-NPWT arm were excluded from the intention-to-treat analysis. For the per protocol analysis, 16 (20%) and 30 (37%) patients were excluded from the s-NPWT and t-NPWT arms, respectively. Randomization was stratified by wound type and wound size. The PICO dressing was set to provide -80 mmHg of negative pressure. Choice of traditional, NPWT device manufacturer and pressure setting was at the discretion of the treating physician, with an average pressure of -118.3 mmHg (median, -125 mmHg; standard deviation [SD], 23.4 mmHg) applied.

The study intended to test for noninferiority in the percentage change of target ulcer area with s-NPWT versus t-NPWT over the course of a 12-week treatment period, with a noninferiority margin of 12.5%. The analysis was performed with the per protocol population to account for dropouts and then repeated on the full analysis set (intention-to-treat). Secondary outcomes included wound closure rate, time to wound closure, and quality of life. Participants and investigators were not blinded, and it is unclear if the study utilized blinded assessors. Patients were seen weekly in outpatient wound centers. After adjustment for baseline wound area, pooled study site, wound type, and wound duration at baseline, the mean percentage difference in wound area over 12 weeks was 27% (96.9% vs. 69.9%; p=.003) in the per protocol analysis and 39.1% (90.24% vs. 51%; p<.001) in the intention-to-treat analysis. This treatment effect was also significant in the diabetic foot ulcer subgroup (p=.031). However, confidence intervals were not reported for the primary outcome.

Confirmed wound closure (intention-to-treat) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted OR of 0.294 (95% CI, 0.135 to 0.638; p=.002) for all wound types and 0.161 (95% CI, 0.035 to 0.744; p=.020) for diabetic foot ulcer. However, the subgroup analysis for diabetic foot ulcer patients in the per protocol population was not significant.

The median estimate of the time to achieve confirmed closure was 77 days for s-NPWT (95% CI, 49 to undefined limit) and could not be calculated for t-NPWT due to the low number of patients achieving this endpoint. No significant differences were noted in health related QOL between baseline and exit visits. Fifty-seven treatment-related adverse events were reported, 16 related to s-NPWT in 12 patients and 41 related to t-NPWT in 29 patients. Wound-related adverse events included increase in target ulcer size, inability to tolerate NPWT, and periwound skin maceration, resulting in study discontinuation by 3 treated with s-NPWT and 9 treated with t-NPWT. While the PICO dressing met noninferiority, change in wound area is not a primary health outcome of interest due to its inherent heterogeneity. Additionally, the chosen treatment duration may have been of insufficient duration to accurately assess effects on wound closure. Required use of fillers, a higher level of negative pressure, and utilization of devices from various t-NPWT manufacturers may have impacted findings. Only 20% of patients in the s-NPWT arm were treated with fillers, mainly in those with diabetic foot ulcer.

A subanalysis of this RCT highlighting outcomes in patients with lower-extremity (foot and venous leg) diabetic ulcers was published by Kirsner and colleagues. The intention-to-treat population included 46 patients in the s-NPWT arm and 49 patients in the t-NPWT arm. The treatment OR for achieving confirmed wound closure at 12 weeks was 0.129 (95% CI, 0.041 to 0.404; p<.001). In the per protocol population, which included 36 patients in the s-NPWT arm and 25 patients in the t-NPWT arm, the treatment OR for confirmed wound closure at 12 weeks was 0.179 (95% CI, 0.044 to 0.735; p=.017). Baseline patient characteristics, including distribution of foot and venous leg ulcers in each treatment arm, were not reported. This analysis is also limited by its retrospective, post-hoc nature and insufficient follow-up duration.

The portable, nonpowered (mechanical) gauze-based SNaP Wound Care System became available in 2009. The device is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers.

In 2011, Armstrong and colleagues reported results of a planned interim analysis of a randomized controlled trial (RCT) comparing the SNaP device and the V.A.C. (Negative pressure therapy Assisted Closure®) Therapy (Kinetic Concepts, Inc., San Antonia, TX) for the treatment of chronic lower extremity wounds. The study randomized 132 patients with lower extremity venous or diabetic ulcers of varying size and present more than 30 days despite appropriate care. Dressings were changed per manufacturer direction, 2 times per week in the SNaP group and 3 times per week in the V.A.C. group. Patients were assessed for up to 16 weeks or until complete wound closure; 83 patients (63%) completed the study. Intention-to-treat analysis with the last observation carried forward showed non-inferiority in the primary outcome of wound size reduction at 4, 8, 12 and 16 weeks. When adjusted for differences in wound size at baseline, Snap-treated subjects showed non-inferiority to the VAC-treated subjects at 4, 12, and 16 weeks. Kaplan-Meier analysis showed no significant difference in complete wound closure between the two groups. At the final follow up, 65.6% of the VAC group and 63.6% of the SNaP group had wound closure. Survey data indicated that dressing changes required less time, and the use of the SNaP device interfered less with mobility and activity than the V.A.C. device. This study is limited by the high loss to follow-up and the lack of comparison with standard treatment protocols.

A 2010 retrospective study with historical controls compared negative pressure wound therapy using the SNaP device (n=28) with wound care protocols that included the use of Apligraf (Novartis), Regranex (Healthpoint Ltd.), and skin grafting (n=42) for treatment of lower extremity ulcers. Seven patients (25%) in the SNaP-treated group could not tolerate the treatment and were discontinued from the study because of complications (allergic skin reaction, wound infection, bleeding after debridement preventing reapplication, worsening lower extremity edema, and the development of maceration severe enough to require discontinuation) and were considered treatment failures. Between-group estimates of time-to-wound healing by Kaplan-Meier analysis favored the SNaP treatment group. The study is limited by the use of historical controls, the multiple modalities used in treatment of controls, and the large number of dropouts. The authors noted that patients in the SNaP treated group may have benefitted from being in an experimental environment, particularly because wounds in this group were seen twice per week compared to variable follow-up in the historical controls.

Section Summary
The evidence on portable, single-use NPWT for diabetic ulcers and amputation wounds includes an RCT of the PICO device and an RCT of the nonpowered SNaP System. A 2019 RCT compared the PICO device with standard NPWT in outpatients with diabetic and venous ulcers. In this study, the PICO device demonstrated noninferiority for wound area reduction. A statistically significant benefit in complete wound closure was noted for patients with diabetic ulcers but was not duplicated in the per protocol population due to

a high number of exclusions. Interpretation of this study is limited by variable device settings and short follow-up duration. One study of the SNaP System showed noninferiority to a V.A.C. device for wound size reduction. No significant difference in complete wound closure was reported. Interpretation of this study is limited by a high loss to follow-up. Well-designed comparative studies with larger numbers of patients powered to detect differences in complete wound closure are needed.

Evidence Review – Lower Extremity Ulcers due to Venous Insufficiency
Kirsner et al (2019) published an RCT that allocated 164 patients with venous leg ulcers (n=104) or diabetic foot ulcers (n=60) to treatment with PICO s-NPWT (n=80) or t-NPWT (n=84). Additional study details and limitations are summarized previously in indication 2.

The primary outcome measure, mean percentage difference in wound area over 12 weeks, was 27% (96.9% vs. 69.9%; p=.003) in the per protocol analysis and 39.1% (90.24% vs. 51%; p<.001) in the intention-to-treat analysis. This treatment effect was also significant in the venous leg ulcer subgroup (p=.007). However, CIs were not reported. Confirmed wound closure (intention-to-treat) was achieved in 54 (33.5%) patients (s-NPWT, 36 [45%]; t-NPWT, 18 [22%]), with an adjusted OR of 0.294 (95% CI, 0.135 to 0.638; p=.002) for all wound types and 0.398 (95% CI, 0.152 to 1.044; p=.061) for venous leg ulcer. The subgroup analysis for venous leg ulcer patients in the per protocol population was also not significant.

Armstrong et al (2011) reported on results of a planned interim analysis of an RCT comparing the SNaP Wound Care System with the V.A.C. Therapy for the treatment of chronic lower-extremity wounds. Final results of this industry-sponsored multicenter noninferiority trial were reported in 2012. Approximately 70% of the study population had venous leg ulcers. Additional study details and limitations are summarized previously in indication 2.

A subgroup analysis (2015) of 40 patients with venous leg ulcers who completed the study showed a significant improvement in the percentage of those with complete wound closure treated with SNaP (57.9%) compared with the V.A.C. system (38.2%; p=.008). However, this study had a high loss to follow-up and lacked a comparison with standard treatment protocols.

Section Summary
The evidence on portable, single-use NPWT for lower-extremity venous ulcers includes an RCT of the PICO device and an RCT of the nonpowered SNaP System. A 2019 RCT compared the PICO device with standard NPWT in outpatients with diabetic and venous ulcers. In this study, the PICO device demonstrated noninferiority for wound area reduction. No significant benefit in complete wound closure was found in patients with venous ulcers. One study of the SNaP System showed noninferiority to a V.A.C. device for wound size reduction. A subgroup analysis of this study found a significant difference in complete wound closure for patients with venous ulcers. However, interpretation of this study is limited by a high loss to follow-up and a lack of a control group treated with

standard dressings. Well-designed comparative studies with larger numbers of patients powered to detect differences in complete wound closure are needed.

Evidence Review – Burn Wounds
For individuals who have burn wounds who receive outpatient NPWT, the evidence includes RCTs, systematic reviews, and case series. An interim report of an RCT evaluating NPWT in partial-thickness burns, summarized in a Cochrane review, did not permit conclusions on the efficacy of NPWT for this indication. A separate RCT comparing NPWT with split-skin grafts in patients with full-thickness burns did not show differences in graft take and wound epithelialization. A retrospective case series reported good functional outcomes for most patients who were treated with NPWT at a single center.

Section Summary
The evidence on NPWT as a primary treatment of partial-thickness burns is limited. A retrospective case series reported good functional outcomes in most patients treated for hand burns with NPWT. One RCT on NPWT for skin grafts showed no benefit for graft take, wound epithelialization, or scar quality.

Evidence Review – Traumatic and Surgical Wounds
PICO is a portable single-use NPWT system that comes with 2 sterile dressings and has a lifespan of 7 to 14 days. Karlakki et al (2016) reported on an RCT with 220 patients that evaluated the use of the PICO device in a surgical center immediately after hip and knee arthroplasties. The device was left on for 7 days, including the time after the hospital stay. Strengths of the trial included powered intention-to-treat analysis, but evaluators were not blinded. There were trends toward reductions in hospital length of stay (0.9 days; 95% CI, -0.2 to 2.5 days; p=.07) and postoperative surgical wound complications (8.4% control vs. 2.0% PICO, p=.06). However, most of the difference in length of stay was due to wound complications in 2 outliers in the control group (up to 61 days). The level of wound exudate was significantly reduced by the PICO device (p=.007), with 4% of the study group and 16% of the control group having grade 4 (scale grade, 0-4) exudate. Blisters were observed in 11% of patients treated with the PICO system, although the blister occurrence was reported to be reduced when the dressing was stretched less.

Peterson et al (2021) reported on a single-site RCT evaluating the PICO system for incisional NPWT following cesarean delivery in women with class III obesity (body mass index ≥40; n=55) compared to standard dressings (n=55). An unplanned interim analysis was performed due to slow enrollment and publication of larger trials reporting no benefit for NPWT. The interim analysis demonstrated no significant difference in the primary composite outcome of wound complications between groups (risk difference, 9.1%; 95% CI, -8.3% to 25.8%; p=.38) and the trial was terminated early.

Pauser et al (2016) reported on a small RCT (n=21) evaluating Prevena in patients who had hemiarthroplasty for femoral neck fractures. Use of the Prevena System significantly

reduced seroma size, days of wound secretion, wound care time, and need for dressing changes.

Murphy et al (2019) published findings from the Negative Pressure Wound Therapy Use to Decrease Surgical Nosocomial Events in Colorectal Resections (NEPTUNE) trial, a single-center, superiority designed prospective randomized open blinded endpoint controlled trial evaluating the use of the Prevena System on closed incisions compared to standard gauze dressings in patients undergoing colorectal resection via laparotomy (n=300). There was no significant difference in the incidence of SSI at 30 days post-surgery between the Prevena and control groups (32% vs. 34%; p=.68). No significant difference in length of hospital stay was reported.

Hussamy et al (2019) reported on an open-label RCT evaluating the Prevena System for incisional NPWT following cesarean delivery in women with class III obesity (body mass index ≥40; n=222) compared to standard dressings (n=219). The overall composite wound morbidity rate was not significantly different between the Prevena and control cohorts (17% vs. 19%; RR, 0.9; 95% CI, 0.5 to 1.4).

Tuuli et al (2020) reported on a large, multicenter RCT evaluating the Prevena System for incisional NPWT following cesarean delivery in women with obesity (body mass index >30; n=806) compared to standard dressings (n=802).[48,] The risk of superficial or deep SSI was not significantly different between groups (difference, 0.36%; 95% CI, -1.46% to 2.19%; p=.70). The trial was terminated following a planned interim analysis which indicated an increased rate of adverse events in the Prevena group (difference, 6.95%; 95% CI, 1.86% to 12.03%; p<.001) and futility for the primary outcome.

Bertges et al (2021) conducted a multicenter RCT evaluating the Prevena System for groin incisions in patients undergoing infrainguinal revascularization (n=118) compared to standard dressing (n=124).[49,] The primary composite outcome of groin wound complications, SSI, major noninfectious wound complications, or graft infections within 30 days of surgery was not significantly different between Prevena and control groups (31% vs. 28%; p=.55).

Section Summary
The evidence on portable single-use NPWT includes RCTs of the PICO device and RCTs of the Prevena Incision Management System. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use after total joint arthroplasty and a single-center RCT of combined in- and outpatient use after cesarean delivery in obese women. The evidence base for the Prevena System is not sufficiently robust for conclusions on efficacy to be drawn. Well-designed comparative studies with larger numbers of patients treated in an outpatient setting are needed.

Summary of Evidence
For individuals who have any wound type (acute or nonhealing) including but not limited to diabetic lower extremity ulcers, lower extremity ulcers due to venous insufficiency,

burn wounds or require traumatic and surgical incision management who receive portable single-use outpatient negative pressure wound therapy (NPWT), the evidence includes systematic reviews and randomized controlled trials (RCTs). While results may have shown some benefits, these benefits were not statistically significant. Trials were also limited by a high loss to follow-up and lack of a control group treated with dressings. These studies are insufficient to draw conclusions regarding efficacy. Well-designed comparative studies to standard of care powered negative pressure would therapy with larger numbers of patients are needed to determine the effects of these technologies with greater certainty. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Practice Guidelines and Position Statements

American College of Physicians
In 2015, the American College of Physicians published guidelines on the treatment of pressure ulcers. The guidelines stated there was low-quality evidence that the overall treatment effect of NPWT did not differ from the standard of care.

Regulatory Status
Numerous disposable negative pressures wound therapy (NPWT) systems have received Class II clearance by the FDA through the 510(k) process.

The SNaP® Wound Care System (Spiracur, Sunnyvale, CA) is a Class II device requiring notification to market but not having U.S. Food and Drug Administration (FDA) premarket approval. It received 510(k) marketing clearance from the FDA in 2009 (K081406) and is indicated for the removal of small amounts of exudate from chronic, acute, traumatic, subacute, and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts.

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. PICO 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.”

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 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."

The FDA granted 510(K) Class II clearance for the ciSNaP Closed Incision System (Spiracur, Sunnyvale, CA) on February 25, 2014. This is a non-powered suction apparatus device intended for negative pressure wound therapy for patients who would benefit from wound management via the application of negative pressure, particularly as the device promotes wound healing through the removal of small amounts of exudate from surgical incisions that continue to drain following sutured or stapled closure.

The Prevena™ Incision Management System was cleared for marketing in June 2010 by FDA under the 510(k) process and 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 NPWT." The predicate device was KCI's Acti V.A.C. (vacuum assisted closure) Therapy System. The customizable dressing was cleared for marketing in October 2012 and was designated as a combination product in March 2014.

The myNeWT Negative Pressure Wound Therapy System (Stortford Medical LLC) was cleared for marketing February 2017 by FDA under the 510(k) process and is intended to promote wound healing by removing low to moderate levels of exudate and infections materials. The appropriate wounds include chronic wounds; acute, sub-acute and dehisced wounds; traumatic wounds; partial thickness burns, pressure or venous insufficiency ulcers, diabetic ulcers, flaps, and grafts; and closed incision sites.

The AVELLE negative pressure wound therapy system (ConvaTec Limited) was cleared for marketing October 2018 by FDA under the 510(K) process and is intended to promote wound healing via removal of exudate and infectious material from low to moderately exuding wound such as: chronic wounds e.g., leg ulcers; acute wounds; subacute and dehisced wounds; traumatic wounds; flaps and graft; and surgically closed incisions sites.

The UNO negative pressure wound through system (Genadyne Biotechnologies, Inc) was cleared for marketing November 2018 by FDA under the 510(k) process and is intended to promote wound healing by the removal of low to moderate exudates and infectious material from the following wound types: chronic; acute; traumatic; subacute and dehisced wounds; partial thickness burns; ulcers (such as diabetic or pressure); flaps and grafts; and closed surgical incision.

extriCARE® 2400 NPWT System (Devon Medical) was cleared for marketing September 2014 by FDA under the 510(k) process and is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The extriCARE® Negative Pressure Wound Therapy System is indicated for the following wound types: chronic, acute, traumatic, subacute, and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

NPWT PRO to GO (Cardinal Health) was cleared for marketing April 2015 by FDA under the 510(k) process and is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

RENASYS™ GO (Smith & Nephew) was cleared for marketing by FDA under the 510(k) process September 2016 indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates, and infectious materials. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns
- Flaps and grafts

XLR8 PLUS (Genadyne Biotechnologies) was cleared for marketing by FDA under the 510(k) process August 2014 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 excess exudates, infectious material and tissue debris.

PRIOR APPROVAL

Not applicable.

POLICY

Note: *This policy applies to the use of non-powered negative pressure wound therapy (NPWT) systems (mechanical or single use (disposable) battery operated devices) in the outpatient setting.*

The use of non-powered negative pressure wound therapy (NPWT) system devices (mechanical) or single use (disposable) battery operated negative pressure wound therapy system devices, including but not limited to the following, are considered **investigational**

for all indications because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- AVELLE Negative Pressure Wound Therapy System
- ciSNaP Closed Incision System
- extriCARE® 2400 Negative Pressure Wound Therapy System
- Invia Motion Negative Pressure Wound Therapy System
- myNeWT Negative Pressure Wound Therapy System
- NPWT PRO to GO
- PICO™ Single Use Negative Pressure Wound Therapy System, PICO™ 7 or PICO™ 7Y Single Use Negative Pressure Wound Therapy System
- Prevena™ Incision Management System, Provena™ Plus Duo Incision Management System, or Provena™ Restor Incision Management System
- RENASYS™ GO
- SNaP® Wound Care System
- UNO Negative Pressure Wound Therapy System (UNO Single Patient Disposable Negative Pressure Wound Therapy System)
- V.A.C. Via™ Therapy System
- XLR8 Plus

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- A9272 Wound suction, disposable, includes dressing and all accessories and components, each.
- 97607 Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
- 97608 Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

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POLICY HISTORY		
Date	**Reason**	**Action**
October 2022	Annual Review	Policy Revised
October 2021	Annual Review	Policy Revised
April 2020	Annual Review	Policy Renewed
April 2019	Annual Review	Policy Revised
April 2018	Annual Review	Policy Revised
April 2017	Annual Review	Policy Revised
April 2016	Annual Review	Policy Renewed
May 2015	Annual Review	Policy Renewed
June 2014	Annual Review	Policy Revised
August 2013	Annual Review	Policy Renewed
September 2012		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
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