

01.01.20 Non-Powered Negative Pressure Wound Therapy

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Related Policies:

- [02.01.60 Amniotic Membrane and Amniotic Fluid Grafts](#)
- [02.01.17 Bio-Engineered Skin and Soft Tissue Substitutes](#)
- [01.01.25 Noncontact Ultrasound Treatment for Wounds](#)

Summary

Description

Note: *This evidence review applies to single-use (disposable) non-powered negative pressure wound therapy (NPWT) systems in the outpatient setting.*

Conventional powered negative pressure wound therapy (NPWT) (vacuum-assisted drainage collection system) can be bulky and intrusive for individuals who are ambulatory and active, single-use disposable non-powered (battery operated) negative pressure wound therapy (NPWT) systems have been proposed for the treatment of small to medium sized, slow to heal wounds and for the management of surgical incisions to promote the formation of granulation of tissue and wound healing.

Summary of Evidence

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. 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 foot ulcers but was not duplicated in the per protocol population due to a high number of exclusions. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lower-extremity ulcers due to venous insufficiency who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. A 2019 RCT compared the PICO device with standard NPWT. 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 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have traumatic or surgical wounds who receive portable, single-use outpatient NPWT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use after total joint arthroplasty and 2 single-center RCTs of combined in- and outpatient use after cesarean delivery in women with obesity or other risk factors for poor wound healing. The evidence base for the Prevena System in the outpatient setting 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of portable, single-use negative pressure wound therapy (NPWT) devices improves outcomes when used for the outpatient treatment of pressure ulcers, diabetic foot ulcers, venous ulcers, burn wounds, and traumatic or surgical wounds.

PRIOR APPROVAL

Not applicable.

For medical necessity clinical coverage criteria using InterQual® criteria related to negative pressure wound therapy (NPWT) electrical pump stationary or portable, refer to Wellmark Authorization Table

POLICY

The use of non-powered negative pressure wound therapy (NPWT) mechanical or single use (disposable) battery operated devices are considered **investigational** for the treatment of acute or chronic wounds, including but not limited to diabetic, venous, surgical and traumatic wounds. The evidence is insufficient to determine the effects of the technology on net health outcomes.

POLICY GUIDELINES

Note: See [Regulatory Status](#) information for FDA approved device information.

Coding

See the [Codes table](#) for details.

BACKGROUND

Chronic Wounds

Management

The management and treatment of chronic wounds, including decubitus ulcers, is challenging. Furthermore, certain racial and ethnic groups, including African Americans, Hispanics, and Native Americans, experience higher diabetes prevalence, contributing to disparities in the risk for diabetic ulcers; these disparities are exacerbated when inequalities in access to health care result in delayed diagnosis and management.

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.

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) 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 infectious materials. The appropriate wounds include chronic wounds; acute, sub-acute and dehiscent 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 dehiscent 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 dehiscent 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 dehiscent 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 dehiscent 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 dehiscent 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.

RATIONALE

This evidence review was developed in September 2012 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 2026.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Portable Single-Use Therapy for Diabetic Lower-Extremity Ulcers and Amputation Wounds

Clinical Context and Therapy Purpose

The purpose of portable, single-use outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with diabetic lower-extremity ulcers or amputation wounds.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with diabetic lower-extremity ulcers or amputation wounds.

Interventions

The therapy being considered is portable, single-use outpatient NPWT, which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators

The following therapies are currently being used to make decisions about the treatment of diabetic-lower extremity ulcers and amputation wounds: standard wound care and standard reusable NPWT devices.

Outcomes

The general outcomes of interest are symptoms, change in disease status, quality of life (QOL), and treatment related morbidity. Though not completely standardized, follow-up for diabetic lower-extremity ulcers or amputation wound symptoms would typically occur in the months to years after starting treatment.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds.

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies conducted exclusively in the inpatient setting were excluded.

Review of Evidence

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 $\geq 30\%$ 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 an increase in target ulcer size, inability to tolerate NPWT, and peri wound 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 sub-analysis 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.

Smart Negative Pressure Wound Care System

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, dehiscent, 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 Antonio, 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: Portable, Single-Use Therapy for Diabetic Lower Extremity Ulcers and Amputation Wounds

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.

Portable, Single-Use Therapy for Lower Extremity Ulcers due to Venous Insufficiency

Clinical Context and Therapy Purpose

The purpose of portable, single-use outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with lower-extremity ulcers due to venous insufficiency.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with lower-extremity ulcers due to venous insufficiency.

Interventions

The therapy being considered is portable, single-use outpatient NPWT (powered or nonpowered), which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators

The following therapies are currently being used to make decisions about the treatment of lower-extremity ulcers due to venous insufficiency: compression therapy, standard wound care, and standard reusable NPWT devices.

Outcomes

The general outcomes of interest are symptoms, change in disease status, quality of life (QOL), and treatment related morbidity. Though not completely standardized, follow-up for lower-extremity ulcers due to venous insufficiency symptoms would typically occur in the months to years after starting treatment.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds.

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

PICO Dressing

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.

Smart Negative Pressure Wound Care System

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: Portable, Single-Use Therapy for Lower Extremity Ulcers due to Venous Insufficiency

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.

Portable, Single-Use Therapy for Traumatic and Surgical Wounds

Clinical Context and Therapy Purpose

The purpose of portable, single-use outpatient NPWT is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with traumatic and surgical wounds.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with traumatic or surgical wounds.

Interventions

The therapy being considered is portable, single-use outpatient NPWT (powered or nonpowered), which is administered in wound clinics and the home care setting. Outpatient NPWT does not include treatment at extended care facilities.

Comparators

The following therapies are currently being used to make decisions about the treatment of traumatic or surgical wounds: compression therapy, standard wound care, and standard reusable NPWT devices.

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.

The primary endpoints of interest for trials of wound healing are as follows, consistent with guidance from the FDA for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds.

- Incidence of complete wound closure.
- Time to complete wound closure (reflecting accelerated wound closure).
- Incidence of complete wound closure following surgical wound closure.
- Pain control.

Hayes Evolving Evidence Review July 2024, PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew) for Cesarean Birth Wound Care (surgical site infection [SSI], wound dehiscence, seroma or hematoma) included eight studies. The studies found no statistically significant differences in rates of surgical infection or wound dehiscence compared to the use of PICO single use negative pressure wound therapy (NPWT) compared with standard dressing treatments. Clinical studies comparing PICO single use negative pressure wound therapy (NPWT) to other commercially available single use negative pressure wound therapy (NPWT)s are needed before its effectiveness over competing treatment alternatives can be verified.

Hayes Health Technology Assessment March 2024, Prophylactic Negative Pressure Wound Therapy in Elective Open Abdominal Surgeries to prevent surgical site infections (SSIs) may show a benefit of NPWT over standard sterile dressing (SSD), however, the current body of evidence is of low quality and has not confirmed these findings and uncertainty remains. Limitations include significant heterogeneity between patient populations, underlying reason for abdominal surgery, and treatment characteristics within the included body of evidence makes it difficult to determine which patients benefit from this form of prophylaxis.

PICO Dressing

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. A similarly designed trial (Gonzalez et.al. 2023) evaluated the PICO system for incisional NPWT following cesarean delivery in women with risk factors for wound complications (diabetes, immunocompromise, chorioamnionitis, rheumatologic disease, history of wound complication, current anticoagulant therapy; n=79) compared to standard dressings (n=75). Patients were followed for up to 6 weeks after cesarean delivery. Results demonstrated that wound complication rates were similar between groups (19.4% vs. 19.7%, respectively; p=.43), as were wound infection rates (9% vs 7%, respectively; p=.70)

Prevena System

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). 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). 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).

Ceppa et al (2023) conducted a multicenter RCT evaluating the Prevena System (n=82) following major elective colorectal or hepatopancreatobiliary surgery compared to conventional wound therapy (n=82). The primary endpoint was the rate of postoperative incisional SSIs evaluated at inpatient day 4 or 5 and postoperative day 30; however, results were not stratified by SSI incidence at a specific time point (ie, inpatient vs outpatient occurrence). Results demonstrated that the overall occurrence of the primary

endpoint did not significantly differ between the Prevena and conventional therapy groups (14% vs. 17%, respectively; $p=.31$).

Section Summary: Portable, Single-Use Therapy for Traumatic and Surgical Wounds

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 2 single-center RCTs of combined in- and outpatient use after cesarean delivery in women with obesity or other risk factors for poor wound healing. The evidence base for the Prevena System in the outpatient setting 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.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	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
HCPCS		
	A9272	Wound suction, disposable, includes dressing and all accessories and components, each
Type of Service	Durable Medical Equipment	
Place of Service	Home/Outpatient	

POLICY HISTORY

Date	Action	Action
March 2026	Annual Review	Policy Renewed
March 2025	Annual Review	Policy Renewed
March 2024	Annual Review	Policy Revised
March 2023	Annual Review	Policy Revised
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	Annual Review	New Policy

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

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