



Louisiana

Vacuum-Assisted Closure of Chronic Wounds (Negative Pressure Wound Therapy)

Policy # 00132

Original Effective Date: 04/14/2003

Current Effective Date: 05/10/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling factors (e.g. diabetes, nutrition, relief of pressure), to be **eligible for coverage**** when patient selection criteria are met.

Patient Selection Criteria for Initial 2-week Therapeutic Trial

Coverage eligibility will be considered when any of the following criteria are met:

- Stage III or IV chronic open wounds (diabetic or pressure ulcers) present for at least 30 days that have failed to heal despite optimal wound care when there is high-volume drainage that interferes with healing and/or when standard dressing cannot be maintained; or
- Traumatic or surgical wounds where there has been a failure of immediate or delayed primary closure, AND there is exposed bone, cartilage, tendon, or foreign material within the wound; or
- Other problematic wounds in patients with clinical conditions known to negatively impact wound healing, which are nonhealing (at least 30 days) despite optimal wound care, and require accelerated formation of granulation tissue that cannot be achieved by other available topical wound treatments, including:
 - Significant risk of infection, such as wound location
 - Immunocompromised status

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- Circulatory or metabolic compromise, e.g. diabetes, malnutrition, small vessel disease, and morbid obesity
- Dehisced wounds of significant size

Patient Selection Criteria for Continuation of Powered NPWT

Continuation of the powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program, may be considered **eligible for coverage**** following an initial 2-week therapeutic trial if the treatment trial has resulted in documented objective improvements in the wound, and if there is ongoing objective improvement during subsequent treatment. Objective improvements in the wound should include the development and presence of healthy granulation tissue, progressive wound contracture and decreasing depth, and/or the commencement of epithelial spread from the wound margins.

Medical record documentation must include all of the following:

- Direct wound evaluation, assessment and management based on standardized wound criteria are performed by an appropriately licensed medical professional. (measurements are required and photographs might be requested for initial coverage requests); and
- At least biweekly (every two weeks) documentation of quantitative measurements of changes in wound/ulcer dimensions and characteristics, including surface area, depth, and serial observations (photographs might be requested for continuing coverage requests); and
- Absence of necrosis; and
- Wound management including the application of treatments that maintain a moist wound environment; and
- Comprehensive disease/condition-specific management programs that provide optimal wound healing environment; and
- Assessment of and/or appropriate intervention to establish and maintain adequate nutritional status; and
- Clinical need for use of vacuum assisted wound closure device in a Stage III or IV or problematic wounds.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company may consider vacuum assisted wound closure devices for the treatment of wounds to be **not medically necessary**** under any of the following conditions:

- Initial coverage criteria are not met; or
- There is presence of necrotic tissue with eschar, if debridement is not attempted; or
- Untreated osteomyelitis exists in the vicinity of the wound; or
- Cancer is present in the wound; or
- There is the presence of a fistula to an organ or body cavity within the vicinity.

Based on review of available data, the Company may consider vacuum assisted wound closure devices for the continuing treatment of wounds to be **not medically necessary**** under any of the following conditions:

- Initial coverage criteria are no longer met; or
- The therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound (i.e. any measurable degree of wound healing has failed to occur over the prior 15- 30 days); or
- The wound has developed evidence of wound complications contraindicating continued NPWT (see below); or
- The wound has healed to the extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments (see below); or
- The vacuum assisted wound closure device has been used for 60 days in the treatment of any wound. Coverage beyond 60 days will be given individual consideration based upon supplemental documentation.

Continuation of healing during use of the NPWT system should be monitored on a frequency of not less than every 14 days. Complete healing of a wound would normally be anticipated if all bone, cartilage, tendons, and foreign material were completely covered, healthy granulation were present to within 5 mm of the surface, and the wound edges were reduced to 2 cm in width or diameter.

Contraindications to the use of NPWT systems include the following conditions as noted by a November 2009 U.S. Food and Drug Administration (FDA) alert: necrotic tissue with eschar,

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untreated osteomyelitis, nonenteric and unexplored fistulae, malignancy in the wound, exposed nerve, exposed anastomotic site, and exposed organ.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers use of powered or non-powered portable, disposable (single-use) NPWT systems and all non-powered NPWT systems (e.g. gauze based SNaP Wound Care System, PICO Single Use Negative Pressure Wound Therapy System, Prevena Incision Management System) for the treatment of acute or chronic wounds, including but not limited to diabetic, venous, surgical incisions, and traumatic wounds to be **investigational**.*

Policy Guidelines

Contraindications to the use of negative pressure wound therapy (NPWT) systems include the following conditions as noted by in a 2009 U.S. Food and Drug Administration (FDA) alert: necrotic tissue with eschar, untreated osteomyelitis, nonenteric and unexplored fistulae, malignancy in the wound, exposed nerve, exposed anastomotic site, and exposed organ.

In a 2011 update, FDA noted additional deaths and injury reports with NPWT since 2009. Although rare, these complications can occur wherever NPWT systems are used, including hospitals, long-term care facilities, and at home. Bleeding was the cause of the most serious adverse events, including deaths. Most reports of wound infection were related to the retention of dressing pieces in the wounds. FDA recommendations for health care providers include the following: select patients for NPWT carefully knowing that NPWT systems are contraindicated for certain wound types, and patient risk factors must be thoroughly considered before use; assure that the patient is monitored frequently in an appropriate care setting by a trained practitioner; be aware of complications associated with dressing changes such as infection and bleeding; be vigilant for potentially life-threatening complications, such as bleeding; and be prepared to take prompt action if they occur. FDA reported that the safety and effectiveness of NPWT systems in newborns, infants, and children had not been established and, currently, there are no NPWT systems cleared for use in these populations.

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

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

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

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

Background/Overview

Chronic Wounds

Management

The management and treatment of chronic wounds, including decubitus ulcers, is challenging. Most chronic wounds will heal only if the underlying cause (ie, venous stasis, pressure, infection) is addressed. Also, cleaning the wound to remove nonviable tissue, microorganisms, and foreign bodies are essential to create optimal conditions for either re-epithelialization (ie, healing by secondary intention) or preparation for wound closure with skin grafts or flaps (ie, healing by primary intention). Therefore, débridement, 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 therapy or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue. The devices may also be used as an adjunct to surgical therapy or as an alternative to surgery in a debilitated patient. Although the exact mechanism has 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.

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A nonpowered (mechanical) NPWT system has also been developed; the Smart Negative Pressure Wound Care System is portable and lightweight (3 oz) and can be worn underneath clothing. This system consists of a cartridge, dressing, and strap; the cartridge acts as the negative pressure source. The system is reported to generate negative pressure levels similar to other NPWT systems. This system is fully disposable.

Powered NPWT devices may be stationary or portable, rely on AC or battery power, allow for regulation of the suction strength, have alarms to indicate loss of suction, and has a replaceable collection canister. Examples of portable rental units include, but may not be limited to:

- ActiV.A.C. Therapy Unit
- Invia Liberty and Invia Motion NPWT Systems
- RENASYS GO
- V.A.C. Freedom Therapy Unit

Non-powered NPWT devices use a mechanical (i.e., spring loaded) device to create a vacuum. These portable, single-use disposable devices are intended to treat smaller wounds. Examples of single-use disposable units include, but may not be limited to:

- Smart Negative Pressure (SNaP) Wound Care System
- PICO Single Use Negative Pressure Wound Therapy Wound System
- MyNeWT Negative Pressure Wound System
- Prevena and Prevena Duo Incision Management System
- UNO Negative Pressure Wound Therapy System
- V.A.C. Via Therapy System

The focus of this evidence review is the use of NPWT in the outpatient setting. It is recognized that patients may begin using the device in the inpatient setting as they transition to the outpatient setting.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Negative pressure therapy or suction devices cleared by the U.S. FDA for treating chronic wounds include, but are not limited to: Vacuum-Assisted Closure[®] Therapy (V.A.C., also known as negative pressure wound therapy; KCI); Versatile 1[™] (V1) Wound Vacuum System (Blue Sky Medical), RENASYS[™] EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical)

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Electronics), SVED^{®‡} (Cardinal Health), and PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew).

Portable systems include the RENASYS^{™‡} GO (Smith & Nephew), XLR8 PLUS (Genadyne Biotechnologies), extriCARE^{®‡} 2400 NPWT System (Devon Medical), the V.A.C. Via^{™‡} (KCI), NPWT PRO to GO (Cardinal Health), and the PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew). The Prevena^{™‡} Incision Management System (KCI) is designed specifically for closed surgical incisions.

A nonpowered NPWT device, the SNaP^{®‡} Wound Care System (Spiracur, acquired by Acelyty in 2015), is a class II device requiring notification to market but not having the FDA premarket approval. In 2009, it was cleared for marketing by the FDA through the 510(k) pathway (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers.

NPWT devices with instillation include the V.A.C. VERAFLOR^{™‡} Therapy device (KCI/Acelity). It was cleared for marketing in 2011 by the FDA through the 510(k) pathway (K103156) and is designed to allow for controlled delivery and drainage of topical antiseptic and antimicrobial wound treatment solutions and suspensions. It is to be used with the V.A.C. Ulta unit, which is commercially marketed for use in the hospital setting. Instillation is also available with Simultaneous Irrigation^{™‡} Technology tubing sets (Cardinal Health) for use with Cardinal Health SVED^{®‡} and PRO NPWT devices, however, its use is not indicated for use in a home care setting (K161418).

No NPWT device has been cleared for use in infants and children.

In November 2009, the FDA issued an alert concerning complications and deaths associated with NPWT systems. An updated alert was issued in February 2011.

FDA product code: OMP.

Rationale/Source

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Negative pressure wound therapy (NPWT) involves the use of 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.

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive outpatient NPWT, the evidence includes randomized controlled trials (RCTs) and a systematic review of RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There was a higher rate of wound healing and fewer amputations with NPWT, although the studies were at risk of bias due to lack of blinding. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have chronic pressure ulcers who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. All trials are of low-quality and at high-risk of bias. Also, most study populations were treated in inpatient settings. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lower-extremity ulcers due to venous insufficiency who receive outpatient NPWT, the evidence includes an RCT and a systematic review. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. A single RCT in patients with nonhealing leg ulcers who were treated with skin grafts found a faster rate of healing with NPWT when used in the inpatient setting. No studies were identified on the effectiveness of NPWT as a primary treatment for leg ulcers or for the use of NPWT in the outpatient setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have burn wounds who receive outpatient NPWT, the evidence includes RCTs, systematic reviews, and case series. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. 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 functional outcomes for most patients

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who were treated with NPWT at a single- center. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have traumatic or surgical wounds who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. There are limited data on NPWT as a primary treatment of partial-thickness burns. One RCT found no benefit of NPWT on graft take and wound epithelialization in patients with full-thickness burns. NPWT showed no benefit in the treatment of patients with surgical wounds or skin grafts healing by primary intention, and a systematic review of NPWT for traumatic and surgical wounds found no differences between standard dressing and NPWT for any wound outcome measure. However, a small RCT has suggested that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. A small retrospective study reported improved epithelialization with NPWT in patients free of comorbidities. Additional study in larger samples is needed to evaluate this outcome measure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have any wound type (acute or nonhealing) who receive portable single-use outpatient NPWT, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The evidence includes an RCT of the PICO Single Use Negative Pressure Wound Therapy System, an RCT of the nonpowered Smart Negative Pressure Wound Care System, and a pseudorandomized study of the Prevena Incision Management System. The PICO device was studied in an adequately powered but unblinded RCT of combined in- and outpatient use following total joint arthroplasty; also, a 2017 RCT compared the PICO device with standard dressing following abdominal surgery. Results showed some benefits, though not statistically significant. One study with the Smart Negative Pressure nonpowered Wound Care System showed noninferiority to a vacuum-assisted closure device. However, interpretation of this trial is limited by a high loss to follow-up and lack of a control group treated with dressings. These studies are insufficient to draw conclusions about its efficacy. Well-designed comparative studies 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 health outcomes.

Overall, the evidence from comparative clinical trials has demonstrated there is a subset of problematic wounds for which the use of NPWT may provide a significant clinical benefit. However, due to clinical variability and limited data, it is not possible to determine prospectively which

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wounds are most likely to respond favorably to NPWT. In addition, clinical input supports a therapeutic trial of NPWT for chronic pressure ulcers that have failed to heal, for traumatic or surgical wounds that have failed to close when there is exposed bone, cartilage, tendon, or foreign material within the wound, and for nonhealing wounds in patients with underlying clinical conditions known to negatively impact wound healing. Therefore, a therapeutic trial of NPWT of not less than 14 days may be considered medically necessary for chronic wounds that have failed to heal, despite intense conventional wound therapy for at least 90 days, or for wounds of at least 30 days that have a high probability of failure to heal due to compounding factors involving the wound and the patient. For continued use of NPWT beyond 14 days to meet criteria for medical necessity, there must be objective evidence of wound healing, such as the development of healthy granulation tissue and progressive wound contracture.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2010. The input was near uniform in support of a therapeutic trial of negative pressure wound therapy (NPWT) for chronic pressure ulcers that have failed to heal; for traumatic or surgical wounds that have failed to close when there is exposed bone, cartilage, tendon, or foreign material within the wound; and for nonhealing wounds in patients with underlying clinical conditions known to negatively impact wound healing. Most input affirmed that therapeutic trials of NPWT for other acute or chronic wounds would not be medically necessary.

Practice Guidelines and Position Statements

International Expert Panel on Negative Pressure Wound Therapy

In 2011, an international expert panel on NPWT provided evidence-based recommendations for the use of NPWT in chronic wounds. The panel made the following recommendations for the use of NPWT (see Table 1).

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Table 1. Recommendations on Use of NPWT in Chronic Wounds

| Condition | Recommendation | Grade ^a |
|----------------------------|---|--------------------|
| Pressure ulcers, grade 3-4 | “NPWT may be used until surgical closure is possible/desirable.” | C |
| | “NPWT should be considered to achieve closure by secondary intention.... to reduce wound dimensions.... [and] to improve the quality of the wound bed.” | B |
| Diabetic foot ulcers | “NPWT must be considered as an advanced wound care therapy.... [and] must be considered to achieve healing by secondary intention.” | A |
| | “NPWT should be considered in an attempt to prevent amputation or reamputation.” | B |
| Ischemic lower-limb wounds | “... NPWT ... may be considered in specialist hands and never as an alternative for revascularisation.” | C |
| | “... NPWT is NOT indicated in acute limb ischemia.” | D |
| Venous leg ulcers | “If first line therapy (compression) is not efficacious, NPWT should be considered to prepare the wound for surgical closure....” | B |

NPWT: negative pressure wound therapy.^a Grade A: based on high-quality meta-analyses, systematic reviews of randomized controlled trials, or randomized controlled trials with very low risk of bias; grade B: based on high-quality systematic reviews of case-control or cohort studies; grade C: based on well-conducted case-control or cohort studies; grade D: based on case series or expert opinion.

International Multidisciplinary Consensus Recommendations

Willy et al (2017) presented evidence-based consensus guidelines on the use of closed incision negative pressure therapy (ciNPT) following surgery. Among the studies found were 100 randomized controlled studies on ciNPT, most of which found an association between the use of ciNPT and improved outcomes. Based on the evidence, the consensus panel recommended that surgeons evaluate risk in patients before surgery to determine whether patient comorbidities (ie, obesity or diabetes) or the nature of the surgery presents an increased danger of infection. In such cases, the panel recommended the use of ciNPT.

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Infectious Diseases Society of America and Surgical Infection Society

Guidelines for the prevention of infections associated with combat-related injuries were endorsed in 2011 by the Infectious Diseases Society of America and the Surgical Infection Society. The guidelines provided an IB recommendation (strong recommendation, moderate-quality evidence) that NPWT should be used to manage open wounds (excluding central nervous system injuries).

The 2012 guidelines from the Society for the diagnosis and treatment of diabetic foot infections stated that no adjunctive therapy has been proved to improve the resolution of infection, but for select diabetic foot wounds that are slow to heal, clinicians might consider using NPWT (weak recommendation, low-quality evidence).

American College of Physicians

The American College of Physicians (2015) 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.

Association for the Advancement of Wound Care

The Association for the Advancement of Wound Care (2010) published guidelines on the care of pressure ulcers. NPWT was included as a potential second-line intervention if first-line treatments did not result in wound healing (level B evidence). The guidelines indicated that patients must be selected carefully for this procedure. The guidelines were updated in 2014 with additional validation.

The Association (2010) supported guidelines on the care of venous ulcers. The guidelines listed NPWT as a potential adjunctive therapy if conservative therapy does not work in 30 days. The guidelines noted there is limited evidence for NPWT (level B) compared with other adjunctive therapies

National Institute for Health and Care Excellence

The NICE (2013) issued guidance on NPWT for surgical wounds, concluding that “Current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen is adequate to support the use of this procedure.”

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A 2016 NICE guidance on diabetic foot problems, updated in 2016, has recommended consideration of NPWT after surgical débridement for diabetic foot ulcers on the advice of the multidisciplinary foot care service. It was noted that the evidence reviewed for NPWT was limited and of low-quality, and that it would be useful to have more evidence for this commonly used treatment.

The NICE (2014) issued guidance on the prevention and management of pressure ulcers. The guidance stated, “Do not routinely offer adults negative pressure wound therapy to treat a pressure ulcer, unless it is necessary to reduce the number of dressing changes (for example, in a wound with a large amount of exudate).” Also, the guidance did not recommend NPWT for neonates, infants, or children.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|----------------|---|--------------------|--------------------|
| <i>Ongoing</i> | | | |
| NCT02664168 | A Prospective, Randomized, Comparative Study to Assess the Prevention of Surgical Site Infection (SSI's) in Revision Total Joint Arthroplasty Patients Treated With Single-Use Negative Pressure Wound Therapy (PICO™) or Standard Care Dressings (AQUACEL® Ag SURGICAL Dressing) | NR | Feb 2020 (unknown) |

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| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|--------------------------|---|---------------------------|--------------------------|
| NCT02348034 ^a | A Randomized Controlled Trial Exploring the Ability of Negative Pressure Wound Therapy (NPWT) to Reduce Colorectal Surgical Site Infections (SSI) | 398 | Jul 2020 (recruiting) |
| NCT02467998 | The Registry of Negative Pressure Wound Therapy for Chronic Wounds and Ulcers (NPWTR) | 50,000 | Jan 2020 (unknown) |
| NCT03144726 | Single Center Prospective Randomized Control Trial on Negative Pressure Wound Therapy for Incisions Following Major Lower-limb Amputation to Reduce Surgical Site Infection | 290 | Jul 2020 (unknown) |
| NCT03716687 | Prophylactic Negative Pressure Wound Therapy for High Risk Laparotomy Wounds: A Randomized Prospective Clinical Trial | 300 | Sep 2020 (recruiting) |
| NCT02509260 | Prevena™ Incisional Negative Pressure Wound Therapy in Re-operative Colorectal Surgery | 298 | May 2021 (recruiting) |
| NCT03414762 | PICO Negative Pressure Wound Therapy in Obese Women Undergoing Elective Cesarean Delivery | 400 | Jul 2021 (recruiting) |
| NCT03948412 | Negative Pressure Wound Therapy (PREVENA) Versus Standard Dressings for Incision Management After Renal Transplant (IMPART) | 500 | Sep 2021 (recruiting) |
| NCT04584957 | Prophylactic Negative Pressure Wound Therapy in Gynecologic Oncology: a Prospective Controlled Randomized Trial (GO-VAC) | 196 | Sep 2021 (ongoing) |
| NCT03773575 ^a | Evaluation of Closed Incision Negative Pressure Dressing (PREVENA) to Prevent Lower Extremity Amputation Wound Complications (PREVENA-AMP) | 440 | Dec 2021 (recruiting) |

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Louisiana

Vacuum-Assisted Closure of Chronic Wounds (Negative Pressure Wound Therapy)

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Current Effective Date: 05/10/2021

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---------------------------|--|---------------------------|-------------------------------|
| NCT02682316 ^a | A Phase III Randomized Controlled Trial of Negative Pressure Wound Therapy in Post-Operative Incision Management | 577 | Feb 2022 (ongoing) |
| NCT04110353 | Prophylactic Closed Incision Negative Pressure Wound Therapy on Abdominal Wounds - Clinical and Economic Perspectives (ProNounCE) | 570 | Jun 2022 (not yet recruiting) |
| NCT04042259 | Delayed Primary Closure Using Negative Pressure Wound Therapy | 350 | Dec 2022 (recruiting) |
| NCT01821664 | Vascular Graft Infections - Epidemiology, Best Treatment Options, Imaging Modalities and Impact of Negative Pressure Wound Therapy | 1800 | Mar 2023 (recruiting) |
| NCT01913132 | PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - A Prospective Randomized Trial | 644 | Dec 2024 (recruiting) |
| NCT02813161 | A Real World, Observational Registry of Diabetic Foot Ulcers and Quality of Care in Clinical Practice (DFUR) | 10,000 | Feb 2025 (recruiting) |
| <i>Unpublished</i> | | | |
| NCT02309944 | Negative Pressure Wound Therapy in Obese Gynecologic Oncology Patients | 93 | June 2020 (completed) |
| NCT02799667 | Randomized Controlled Trial: Do Single Use Negative Pressure Dressings Reduce Wound Complications in Women With a BMI >40 kg/m ² Undergoing Cesarean Delivery at a Tertiary Medical Center? | 110 | Terminated |

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|--------------------------|---|---------------------------|------------------------|
| NCT01191567 | Negative Pressure Wound Therapy. Therapy Effects and the Impact on the Patient's Quality of Life | 200 | Terminated |
| NCT02470806 ^a | A Prospective, Randomized, Comparative Effectiveness Study of a Single-Use, Negative Pressure Wound Therapy System (PICO) Versus a Traditional Negative Pressure Wound Therapy System (tNPWT) in the Treatment of Lower Extremity Ulcers | 164 | Nov 2017 (completed) |
| NCT02395159 | Reduction of Groin Wound Infections After Vascular Surgery in Patients With Risk Factors by the Use a Negative Pressure Wound Incision Management System (KCI Prevena) | 204 | Oct 2017 (completed) |
| NCT02739191 | Negative Pressure Wound Therapy for Surgical Wounds of the Foot and Ankle | 60 | Aug 2017 (completed) |
| NCT02195310 ^a | The Use of Prevena TM Incision Management System on Clean Closed Sternal Midline Incisions in Subjects at High Risk for Surgical Site Occurrences | 342 | Terminated |
| NCT02064270 ^a | A Prospective, Randomized, Controlled Clinical Study to Assess the Prevention of Postsurgical Incision Healing Complications in Patients Undergoing Primary or Revision Total Knee Arthroplasty (TKA) or Total Hip Arthroplasty (THA), Treated With Either Single-Use Negative Pressure Wound Therapy (NPWT) or Standard Postsurgical Dressings | 526 | Sep 2017 (completed) |

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| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|--------------------------|--|--------------------|----------------------|
| NCT01890720 ^a | Use of Incisional Negative Pressure Wound Therapy for Prevention of Postoperative Infections Following Caesarean Section in Women With BMI ≥ 30 | 876 | Dec 2016 (completed) |

NCT: national clinical trial; NR: not reported.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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02/20/2003 Medical Policy Committee review

04/14/2003 Managed Care Advisory Council approval

01/31/2004 Medical Director review

02/17/2004 Medical Policy Committee review. Format revision. No substance change to policy.

02/23/2004 Managed Care Advisory Council approval

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| | |
|------------|--|
| 02/01/2005 | Medical Director review |
| 02/15/2005 | Medical Policy Committee review |
| 03/07/2005 | Managed Care Advisory Council approval |
| 03/09/2006 | Medical Director review |
| 03/15/2006 | Medical Policy Committee review. Format revision. Coverage eligibility unchanged. |
| 04/05/2006 | Medical Director review |
| 04/19/2006 | Medical Policy Committee approval |
| 07/07/2006 | Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged |
| 03/14/2007 | Medical Director review |
| 03/21/2007 | Medical Policy Committee approval. Coverage eligibility unchanged. |
| 03/12/2008 | Medical Director review |
| 03/19/2008 | Medical Policy Committee approval. Coverage eligibility unchanged. |
| 04/02/2008 | Medical Director review |
| 04/16/2008 | Medical Policy Committee approval. No change to coverage eligibility. |
| 04/02/2009 | Medical Director review |
| 04/15/2009 | Medical Policy Committee approval. No change to coverage eligibility. |
| 04/08/2010 | Medical Director review |
| 04/21/2010 | Medical Policy Committee approval. No change to coverage eligibility. |
| 04/07/2011 | Medical Policy Committee review |
| 04/13/2011 | Medical Policy Implementation Committee approval. No change to coverage eligibility. |
| 04/12/2012 | Medical Policy Committee review |
| 04/25/2012 | Medical Policy Implementation Committee approval. No change to coverage eligibility. |
| 04/04/2013 | Medical Policy Committee review |
| 04/24/2013 | Medical Policy Implementation Committee approval. No change to coverage eligibility. |
| 04/03/2014 | Medical Policy Committee review |
| 04/23/2014 | Medical Policy Implementation Committee approval. No change to coverage eligibility. |
| 04/02/2015 | Medical Policy Committee review |

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- 04/20/2015 Medical Policy Implementation Committee approval. No change to coverage eligibility.
- 04/07/2016 Medical Policy Committee review
- 04/20/2016 Medical Policy Implementation Committee approval. No change to coverage eligibility.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 04/06/2017 Medical Policy Committee review
- 04/19/2017 Medical Policy Implementation Committee approval. Added continuation approval criteria and a new investigational statement.
- 04/05/2018 Medical Policy Committee review
- 04/18/2018 Medical Policy Implementation Committee approval. Criteria clarified documentation every 2 weeks for recertification.
- 04/04/2019 Medical Policy Committee review
- 04/24/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/02/2020 Medical Policy Committee review
- 04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/01/2021 Medical Policy Committee review
- 04/14/2021 Medical Policy Implementation Committee approval. Investigational statement changed to “Based on review of available data, the Company considers use of powered or non-powered portable, disposable (single-use) NPWT systems and all non-powered NPWT systems (e.g. gauze based SNaP Wound Care System, PICO Single Use Negative Pressure Wound Therapy System, Prevena Incision Management System) for the treatment of acute or chronic wounds, including but not limited to diabetic, venous, surgical incisions, and traumatic wounds to be investigational.

Next Scheduled Review Date: 04/2022

Coding

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descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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| Code Type | Code |
|------------------|---|
| CPT | 97605, 97606, 97607, 97608 |
| HCPCS | A6550, A9272, E2402, K0743, K0744, K0745, K0746 |
| ICD-10 Diagnosis | All related diagnoses |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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