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

Policy # 00132
Original Effective Date: 04/14/2003
Current Effective Date: 05/13/2024

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

- 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.

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,

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 single-use (disposable) NPWT systems (powered or non-powered), 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 NPWT systems include the following conditions as noted 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. Recommendations for health care providers include the following: select individuals for NPWT carefully knowing that NPWT systems are contraindicated for certain wound types, and individual risk factors must be thoroughly considered before use; assure that the individual 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. The 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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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. 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 (ie, 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 (ie, healing by secondary intention) or preparation for wound closure with skin grafts or flaps (ie, 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 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.

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.

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; 3M™/KCI)‡; Versatile 1™‡ (V1) Wound Vacuum System (Blue Sky Medical), RENASYS™‡ EZ PLUS (Smith & Nephew), Foryou NPWT NP32 Device (Foryou Medical Electronics), SVED®‡ (Cardinal Health), and PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew).

Disposable systems include:

- AVELLE Negative Pressure Wound Therapy System
- extriCARE®‡2400 NPWT System (Devon Medical)
- V.A.C. Via™‡ Therapy System (KCI)
- NPWT PRO to GO (Cardinal Health)
- Invia Motion Negative Pressure Wound Therapy System
- myNeWT Negative Pressure Wound Therapy System
- PICO™‡ Single Use Negative Pressure Wound Therapy System (Smith & Nephew)
- Prevena™‡ Incision Management System (KCI), Prevena™‡ Plus Duo Incision Management System, and Prevena™‡ Restor Incision Management System are designed specifically for closed surgical incisions

- Uno Negative Pressure Wound Therapy System
- A nonpowered (mechanical) NPWT device, the SNaP®‡ Wound Care System (now SNAP™ Therapy System)‡ (3M™/ previously Spiracur, acquired by Acelity 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.

Negative pressure wound therapy devices with instillation include the V.A.C. VERAFLO™‡ Therapy device (3M™/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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Negative pressure wound therapy involves the use of negative pressure or suction devices to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue and wound healing.

Summary of Evidence
For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive outpatient NPWT, the evidence includes systematic reviews of randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), 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 an improvement in the net health outcome.

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 chronic pressure ulcers who receive outpatient NPWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, 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 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 outpatient NPWT, the evidence includes an RCT and a systematic review. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, 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 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 burn wounds who receive outpatient NPWT, the evidence includes RCTs, systematic reviews, and case series. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, 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 good functional outcomes for most patients who were treated with NPWT at a single center. 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 NPWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Systematic reviews of RCTs in patients with surgical wounds have generally found lower risk of SSI; however, many studies are limited to short-term use of NPWT limiting applicability to the outpatient setting. For patients with traumatic wounds, a

Cochrane review failed to find significant improvement in patients treated with NPWT. 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 a single-center RCT of combined in- and outpatient use after cesarean delivery in women with obesity. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

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 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.

2010 Input
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 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
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.

American Academy of Orthopaedic Surgeons
The American Academy of Orthopaedic Surgeons (AAOS) 2022 guidelines for prevention of surgical site infections after major extremity trauma included recommendations for NPWT. The recommendations from AAOS do not support the continued use of NPWT in patients undergoing fracture fixation due to similar outcomes to standard wound care but with increased healthcare burden. In patients with high-risk surgical incisions the AAOS recommends that limited evidence suggests NPWT may be an option; however, its use will be influenced by cost. Importantly, these guidelines do not specifically address use in the outpatient setting.

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.

Infectious Diseases Society of America and Surgical Infection Society
A 2023 guideline from the Society for the diagnosis and treatment of diabetic-related foot infections (DFIs) makes the following recommendation relevant to NPWT: "We suggest *not* using the following treatments to address DFIs: (a) adjunctive granulocyte colony-stimulating factor (G-CSF) treatment or (b) topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative-pressure wound therapy (with or without instillation)." This was graded as a conditional recommendation with low-quality evidence.

American College of Physicians
In 2015, the American College of Physicians published guidelines (now inactive) 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. Of note, the American College of Physicians considers these guidelines inactive since they are more than 5 years old.

Association for the Advancement of Wound Care
In 2010, the Association for the Advancement of Wound Care (AAWC) published guidelines on the care of pressure ulcers. Negative pressure wound therapy 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.

In 2010, the AAWC published 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
In 2013, NICE issued guidance on NPWT for surgical wounds, concluding that "current evidence on the safety and efficacy of NPWT for the open abdomen is adequate to support the use of this procedure."

A 2015 NICE guidance on diabetic foot problems, updated in October 2019, has recommended consideration of NPWT after surgical debridement 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.

In 2014, NICE 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.

A 2019 NICE guidance recommends the use of the PICO7 negative pressure wound dressing for closed surgical incisions due to their association with fewer surgical site infections and seromas compared to standard wound dressings. The device is considered an option for those who are at high risk for surgical site infections, which may be driven by several factors (eg, age, underlying illness, obesity, smoking, wound classification, and site and complexity of procedure). The device is recommended for those with low to moderate levels of wound exudate who will require infrequent dressing changes.

An updated 2021 NICE guidance on cesarean birth recommends considering the use of NPWT for women with a body mass index $\geq$35 kg/m^2 to reduce the risk of wound infections. Routine use of NPWT following cesarean delivery is not recommended. These recommendations were unchanged in a 2023 update to this guidance.

A 2021 NICE guidance states that while the V.A.C. Veraflo Therapy system shows promise in the treatment of acute infected or chronic non-healing wounds, there is not enough high-quality evidence to support the case for routine adoption. The guidance recommends research in the form of an RCT comparing the V.A.C. Veraflo Therapy system (NPWT with wound instillation) to NPWT alone.

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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 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05877378	Efficacy of PICO Single-use System in Chronic Ulcers	42	Apr 2024
NCT05389410	Comparison of Surgical Wound Healing and Complications Following Revision Hip and Knee Replacements, Utilizing a 7-day Versus 14-day Negative Pressure Wound Therapy (NPWT) Dressing. A Randomized Controlled Trial	100	Nov 2023
NCT05064696	Prospective Comparison of Wound Complications After Anterior Total Ankle Arthroplasty With and Without PICO Negative Pressure Incisional Dressing	150	Sep 2025
NCT05071443	Vacuum-Assisted Closure for Necrotizing Soft Tissue Infections	130	Jun 2025
NCT05266053	Negative Pressure Wound Therapy-PICO: Cosmesis in Repeat C-Sections	100	May 2023

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05615844	A Randomized Controlled Trial Comparing Antibiotic Cement Bead Pouch Versus Negative Pressure Wound Therapy for the Management of Severe Open Tibia Fracture Wounds	312	Mar 2025
NCT03414762	PICO Negative Pressure Wound Therapy in Obese Women Undergoing Elective Cesarean Delivery	153	Sep 2022
NCT03773575[a]	Evaluation of Closed Incision Negative Pressure Dressing (PREVENA) to Prevent Lower Extremity Amputation Wound Complications (PREVENA-AMP)	440	Aug 2024
NCT02682316[a]	A Phase III Randomized Controlled Trial of Negative Pressure Wound Therapy in Post-Operative Incision Management	577	Aprl 2024
NCT04042259	Delayed Primary Closure Using Negative Pressure Wound Therapy	350	Dec 2024
NCT01913132	PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - A Prospective Randomized Trial	644	Dec 2024
NCT02813161	A Real World, Observational Registry of Diabetic Foot Ulcers and Quality of Care in Clinical Practice (DFUR)	10,000	Feb 2025
Unpublished			
NCT04584957	Prophylactic Negative Pressure Wound Therapy in Gynecologic Oncology: a Prospective Controlled Randomized Trial (GO-VAC)	196	Sep 2021

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03948412	Negative Pressure Wound Therapy (PREVENA) Versus Standard Dressings for Incision Management After Renal Transplant (IMPART)	500	Sep 2021
NCT02509260	Prevena™ Incisional Negative Pressure Wound Therapy in Re-operative Colorectal Surgery	298	Feb 2021 (completed)
NCT02348034[a]	A Randomized Controlled Trial Exploring the Ability of Negative Pressure Wound Therapy (NPWT) to Reduce Colorectal Surgical Site Infections (SSI)	126	Dec 2020 (completed)
NCT02309944	Negative Pressure Wound Therapy in Obese Gynecologic Oncology Patients	93	June 2020 (completed)
NCT01191567	Negative Pressure Wound Therapy. Therapy Effects and the Impact on the Patient's Quality of Life	200	Terminated
NCT02195310[a]	The Use of Prevena™ Incision Management System on Clean Closed Sternal Midline Incisions in Subjects at High Risk for Surgical Site Occurrences	342	Terminated

NCT: national clinical trial; NR: not reported.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

Original Effective Date: 04/14/2003
Current Effective Date: 05/13/2024

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
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

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. All of the coverage statements were revised. See below:

Eligible statement revised to:

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
    - 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.

Not Medically Necessary statement revised to:

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.

Investigational section revised 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.***

04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Added "single-use (disposable) NPWT systems (powered or non-powered)" to investigational statement.
04/27/2023	Coding update. Updated FDA section to include only disposable systems.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 04/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

Policy # 00132
Original Effective Date: 04/14/2003
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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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
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 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.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.