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

Policy # 00132
Original Effective Date: 04/14/2003
Current Effective Date: 05/11/2020

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 to be **eligible for coverage**** when patient selection criteria are met.

Patient Selection Criteria
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, and demonstrated failure of conventional wound treatment measures; or
- Stage III or IV chronic open wounds (diabetic or pressure ulcers) present for at least 30 days, and the use of conventional wound treatment measures has been considered and ruled out; or
- Other problematic wounds requiring the need for accelerated formation of granulation tissue that cannot be achieved by other available topical wound treatments, involving:
    - Significant risk of infection, such as wound location
    - Immunocompromised status
    - Circulatory or metabolic compromise
    - Failed conservative treatment
    - Dehisced wounds of significant size

Patient Selection Criteria
Continuation Approval Criteria:

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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
- In the judgment of the treating physician, adequate wound healing has occurred to the degree that the vacuum assisted wound care device can be discontinued; or
- Any measurable degree of wound healing has failed to occur over the prior 30 days; 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 use of nonpowered NPWT systems (e.g. gauze based SNaP system, portable PICO single-use system, Prevena single-use system) for the treatment of acute or chronic 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.

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.

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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.

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. Food and Drug Administration (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 Electronics), 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), 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 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) (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. VERAFLO™‡ 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.

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

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 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 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).

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 amputatio 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.

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."

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
Ongoing			
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)		Feb 2020 (recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01528033[a]	Treatment Study of Vacuum-Assisted Closure for Postsurgical Subcutaneous Abdominal Wound Healing Impairments (SAWHI)	550	Jun 2018 (unknown)
NCT02309944	Negative Pressure Wound Therapy in Obese Gynecologic Oncology Patients	200	Dec 2020 (ongoing)
NCT02509260	Prevena™ Incisional Negative Pressure Wound Therapy in Re-operative Colorectal Surgery	298	Dec 2019 (recruiting)
NCT01913132	PICO Versus Standard Dressing Above Groin Incisions After Vascular Surgery - a Prospective Randomized Trial	644	Apr 2020 (recruiting)
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)
NCT02954835	Negative Pressure Therapy for Closed Groin Wounds in Patients Undergoing Vascular Surgery	100	Dec 2019 (recruiting)
NCT02467998	The Registry of Negative Pressure Wound Therapy for Chronic Wounds and Ulcers	50,000	Jan 2020 (recruiting)
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
NCT02682316[a]	A Phase III Randomized Controlled Trial of Negative Pressure Wound Therapy in Post-Operative Incision Management	686	Feb 2021 (recruiting)
NCT01821664	Vascular Graft Infections - Epidemiology, Best Treatment Options, Imaging Modalities and Impact of Negative Pressure Wound Therapy	1800	Mar 2023 (recruiting)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02813161	A Real World, Observational Registry of Diabetic Foot Ulcers and Quality of Care in Clinical Practice	10,000	Feb 2025 (recruiting)
Unpublished			
NCT02799667	Randomized Controlled Trial: Do Single Use Negative Pressure Dressings Reduce Wound Complications in Women With a BMI >40 kg/m2 Undergoing Cesarean Delivery at a Tertiary Medical Center?	110	Terminated
NCT02020018[a]	Negative Pressure Wound Therapy for Prevention of Wound Infection After Heart Surgery	1869	Oct 2018 (completed)
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	163	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

NCT No.	Trial Name	Planned Enrollment	Completion Date
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)
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.
[a] Denotes industry-sponsored or cosponsored trial.

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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
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.

Next Scheduled Review Date: 04/2021

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 2019 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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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 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.

**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.

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

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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.