MEDICAL POLICY

POLICY TITLE	NEGATIVE PRESSURE WOUND THERAPY IN THE OUTPATIENT SETTING
POLICY NUMBER	MP-4.004

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I. POLICY

Powered negative pressure therapy 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, relief of pressure, etc.

INITIATION OF A POWERED NEGATIVE PRESSURE WOUND THERAPY (NPWT): An initial therapeutic trial of not less than 2 weeks using a powered negative pressure wound therapy (NPWT) system, as part of a comprehensive wound care program that includes controlling factors such as diabetes, nutrition, relief of pressure, etc., may be considered **medically necessary** in the following indications:

- Chronic (> 30 days) stage III or IV pressure ulcers that have failed to heal despite optimal wound care when there is high-volume drainage that interferes with healing and/or when standard dressings cannot be maintained due to anatomic factors, **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**
- Wounds in patients with underlying clinical conditions which are known to negatively impact wound healing, which are non-healing (at least 30 days), despite optimal wound care. Examples of underlying conditions include, but are not limited to diabetes, malnutrition, small vessel disease, and morbid obesity. Malnutrition, while a risk factor, must be addressed simultaneously with the negative pressure wound therapy.

It is not required that a patient be homebound to receive nursing services in the patient's home for wound care using NPWT.

NPWT will be denied at any time as **not reasonable and necessary** if one or more of the following are present:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure;
- Cancer present in the wound;
- The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

Therapeutic trials of powered NPWT systems for the treatment of other acute or chronic wounds except as noted above are considered **not medically necessary**.

CONTINUATION OF POWERED NPWT:
Continuation of the powered NPWT system, as part of a comprehensive wound care program, may be considered **medically necessary** 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.

NPWT may be considered **medically necessary** when continuation of treatment is ordered beyond discharge to the home setting.

Continuation of the powered NPWT system is considered **not medically necessary** when any of the following occurs:

- The therapeutic trial or subsequent treatment period has not resulted in documented objective improvement in the wound, **OR**
- The wound has developed evidence of wound complications contraindicating continued NPWT, **OR**
- The wound has healed to an extent that either grafting can be performed or the wound can be anticipated to heal completely with other wound care treatments.

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

Note: 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.

LENGTH OF COVERAGE
When medically necessary criteria are met, coverage for NPWT may be eligible for up to a maximum of four (4) months (including the time NPWT was applied, regardless of the place of application [e.g., home, inpatient facility]).

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NON-POWERED NPWT

Use of non-powered NPWT systems for the treatment of acute or chronic wounds is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

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 fistulas, malignancy in the wound, exposed nerve, exposed anastomotic site, and exposed organ.

In a 2011 update, the 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. The majority of reports of wound infection were related to the retention of dressing pieces in the wounds. FDA recommendations for healthcare 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. The FDA reported that the safety and effectiveness of NPWT systems in newborns, infants and children has not been established at this time and currently, there are no NPWT systems cleared for use in these populations.

Cross-references:

MP-4.028 Wound and Burn Care and Specialized Treatment Centers
MP-2.033 Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Would Healing and Other Non–Orthopedic Conditions.
MP-2.070 Hyperbaric Oxygen Pressurization
MP-1.017 Bio-Engineered Skin and Soft Tissue Substitutes
MP-1.004 Cosmetic and Reconstructive Surgery
MP-6.026 Durable Medical Equipment (DME)
MP-8.001 Physical Medicine and Specialized Physical Medicine Treatments (Outpatient)

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

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FEP PPO - Refer to FEP Medical Policy Manual MP-1.01.16, Negative Pressure Wound Therapy in the Outpatient Setting. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Negative pressure wound therapy (NPWT) consists of the use of a negative pressure or suction device to aspirate and remove fluids, debris, and infectious materials from the wound bed to promote the formation of granulation tissue and wound healing. The devices may also be used as an adjunct to surgical therapy or as an alternative to surgery in a debilitated patient.

Management

The management and treatment of chronic wounds, including decubitus ulcers, remain a treatment challenge. Most chronic wounds will heal only if the underlying cause, i.e., venous stasis, pressure, infection, etc., is addressed. In addition, cleaning the wound to remove nonviable tissue, microorganisms, and foreign bodies is essential to create the optimal conditions for either re-epithelialization (i.e., healing by secondary intention) or preparation for wound closure with skin grafts or flaps (i.e., healing by primary intention). Therefore, debridement, irrigation, whirlpool treatments, and wet-to-dry dressings are common components of chronic wound care.

Negative pressure wound therapy (NPWT) consists of 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 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 non-powered (mechanical) NPWT system has also been developed; one device is the Smart Negative Pressure (SNaP) Wound Care System. This device 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 document is on 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.

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Regulatory Status

Negative pressure therapy or suction devices cleared by the U.S. Food and Drug Administration (FDA) for the purpose of 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 from Spiracur, is a class II device requiring notification to market but not having FDA premarket approval. In 2009, it was cleared for marketing by 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.

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

In November 2009, FDA issued an alert concerning complications and deaths associated with NPWT systems. An updated alert was issued in February 2011.[1]

FDA product code: OMP.

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have diabetic lower-extremity ulcers or amputation wounds who receive outpatient negative pressure wound therapy (NPWT), the evidence includes randomized controlled trials (RCTs) and a systematic review of RCTs. 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. 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. In addition, 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 1 RCT and a systematic review. 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 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 and systematic reviews. 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 in partial-thickness burns. 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. 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. 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, 1 small RCT has suggested that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. 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. 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 (SNaP) 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. Results showed some benefits that approached statistical significance. Further study in an outpatient setting is needed. One study with the SNaP 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 the technology with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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ATMOSPHERIC PRESSURE is the pressure exerted by the weight of the atmosphere, also known as barometric pressure.

COMPREHENSIVE WOUND CARE PROGRAM includes a minimum of all the following general measures:

- Documentation in the patient's medical record of evaluation, care and wound measurements by a licensed medical professional; and
- Application of dressings to maintain a moist wound environment; and
- Debridement of necrotic tissue when present; and
- Evaluation of and provision for adequate nutritional and vascular status

GRANULATING TISSUE refers to formation of granule-like projections on the internal surface of the wound that represents the outgrowth of new capillaries, bringing a rich blood supply to the wound, promoting healing.

PRESSURE (DECUBITUS) ULCER is a type of wound that forms as a result of prolonged pressure against areas of the skin. This is commonly seen over the bony prominences, such as sacrum and heels, in bedridden and/or wheelchair confined individuals. Pressure ulcers are classified into four stages (and an unstageable category), to signify the degree of skin damage:

Stage I- Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.

Stage II- Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.

Stage III- Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.

Stage IV- Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunneling.

Unstageable- Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. (Until enough slough and/or eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined.)

VASCULARITY is the state of blood vessel development and functioning in an organ or tissue.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Investigational; therefore, not covered:

HCPCS Code	Description
A9272	Mechanical wound suction, disposable, includes dressing, all accessories and components, each

Covered when medically necessary:

CPT Codes®						
97605	97606	97607	97608			

HCPCS Codes	Description
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
A7000	Canister, disposable, used with suction pump, each
A7001	Canister, nondisposable, used with suction pump, each
E2402	Negative pressure wound therapy electrical pump, stationary or portable
K0743	Suction pump, home model, portable, for use on wounds
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq. in or less
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 sq. in but less than or equal to 48 sq. in
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq. in

ICD-10-CM Diagnosis Code	Description
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle

I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot
I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot
I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot
I83.011	Varicose veins of right lower extremity with ulcer of thigh
I83.012	Varicose veins of right lower extremity with ulcer of calf
I83.013	Varicose veins of right lower extremity with ulcer of ankle
I83.014	Varicose veins of right lower extremity with ulcer of heel and midfoot
I83.015	Varicose veins of right lower extremity with ulcer other part of foot
I83.021	Varicose veins of left lower extremity with ulcer of thigh
I83.022	Varicose veins of left lower extremity with ulcer of calf
I83.023	Varicose veins of left lower extremity with ulcer of ankle
I83.024	Varicose veins of left lower extremity with ulcer of heel and midfoot
I83.025	Varicose veins of left lower extremity with ulcer other part of foot
I87.311	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312	Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313	Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
L89.003	Pressure ulcer of unspecified elbow, stage 3
L89.004	Pressure ulcer of unspecified elbow, stage 4
L89.013	Pressure ulcer of right elbow, stage 3
L89.014	Pressure ulcer of right elbow, stage 4
L89.023	Pressure ulcer of left elbow, stage 3
L89.024	Pressure ulcer of left elbow, stage 4
L89.103	Pressure ulcer of unspecified part of back, stage 3
L89.104	Pressure ulcer of unspecified part of back, stage 4
L89.113	Pressure ulcer of right upper back, stage 3
L89.114	Pressure ulcer of right upper back, stage 4
L89.123	Pressure ulcer of left upper back, stage 3
L89.124	Pressure ulcer of left upper back, stage 4
L89.133	Pressure ulcer of right lower back, stage 3
L89.134	Pressure ulcer of right lower back, stage 4
L89.143	Pressure ulcer of left lower back, stage 3
L89.144	Pressure ulcer of left lower back, stage 4
L89.153	Pressure ulcer of sacral region, stage 3
L89.154	Pressure ulcer of sacral region, stage 4

L89.203	Pressure ulcer of unspecified hip, stage 3
L89.204	Pressure ulcer of unspecified hip, stage 4
L89.213	Pressure ulcer of right hip, stage 3
L89.214	Pressure ulcer of right hip, stage 4
L89.223	Pressure ulcer of left hip, stage 3
L89.224	Pressure ulcer of left hip, stage 4
L89.303	Pressure ulcer of unspecified buttock, stage 3
L89.304	Pressure ulcer of unspecified buttock, stage 4
L89.313	Pressure ulcer of right buttock, stage 3
L89.314	Pressure ulcer of right buttock, stage 4
L89.323	Pressure ulcer of left buttock, stage 3
L89.324	Pressure ulcer of left buttock, stage 4
L89.43	Pressure ulcer of contiguous site of back, buttock and hip, stage 3
L89.44	Pressure ulcer of contiguous site of back, buttock and hip, stage 4
L89.503	Pressure ulcer of unspecified ankle, stage 3
L89.504	Pressure ulcer of unspecified ankle, stage 4
L89.513	Pressure ulcer of right ankle, stage 3
L89.514	Pressure ulcer of right ankle, stage 4
L89.523	Pressure ulcer of left ankle, stage 3
L89.524	Pressure ulcer of left ankle, stage 4
L89.603	Pressure ulcer of unspecified heel, stage 3
L89.604	Pressure ulcer of unspecified heel, stage 4
L89.613	Pressure ulcer of right heel, stage 3
L89.614	Pressure ulcer of right heel, stage 4
L89.623	Pressure ulcer of left heel, stage 3
L89.624	Pressure ulcer of left heel, stage 4
L89.813	Pressure ulcer of head, stage 3
L89.814	Pressure ulcer of head, stage 4
S31.100D	Unspecified open wound of abdominal wall, right upper quadrant without penetration into peritoneal cavity, subsequent encounter
S31.100S	Unspecified open wound of abdominal wall, right upper quadrant without penetration into peritoneal cavity, sequela
S31.101D	Unspecified open wound of abdominal wall, left upper quadrant without penetration into peritoneal cavity, subsequent encounter
S31.101S	Unspecified open wound of abdominal wall, left upper quadrant without penetration into peritoneal cavity, sequela
S31.102D	Unspecified open wound of abdominal wall, epigastric region without penetration into peritoneal cavity, subsequent encounter
S31.102S	Unspecified open wound of abdominal wall, epigastric region without penetration into peritoneal cavity, sequela

S31.103D	Unspecified open wound of abdominal wall, right lower quadrant without penetration into peritoneal cavity, subsequent encounter
S31.103S	Unspecified open wound of abdominal wall, right lower quadrant without penetration into peritoneal cavity, sequela
S31.104D	Unspecified open wound of abdominal wall, left lower quadrant without penetration into peritoneal cavity, subsequent encounter
S31.104S	Unspecified open wound of abdominal wall, left lower quadrant without penetration into peritoneal cavity, sequela
S31.105D	Unspecified open wound of abdominal wall, periumbilic region without penetration into peritoneal cavity, subsequent encounter
S31.105S	Unspecified open wound of abdominal wall, periumbilic region without penetration into peritoneal cavity, sequela
T81.31XA	Disruption of external operation (surgical) wound, not elsewhere classified, initial encounter
T81.31XD	Disruption of external operation (surgical) wound, not elsewhere classified, subsequent encounter
T81.32XA	Disruption of internal operation (surgical) wound, not elsewhere classified, initial encounter
T81.32XD	Disruption of internal operation (surgical) wound, not elsewhere classified, subsequent encounter
T81.33XA	Disruption of traumatic injury wound repair, initial encounter
T81.33XD	Disruption of traumatic injury wound repair, subsequent encounter
T81.42XA	Infection following a procedure, deep incisional surgical site, initial encounter
T81.42XD	Infection following a procedure, deep incisional surgical site, subsequent encounter
T81.49XA	Infection following a procedure, other surgical site, initial encounter
T81.49XD	Infection following a procedure, other surgical site, subsequent encounter

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X. POLICY HISTORY

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MP 4.004	**CAC 2/25/03**
	CAC 3/25/03
	CAC 2/22/05
	CAC 3/29/05
	Retire Policy Use InterQual Criteria effective 7/1/06
	CAC 2/27/07
	CAC 5/27/08
	CAC 11/25/08
	CAC 11/24/09 Consensus Review
	CAC 11/30/10 Medicare Variation
	CAC 6/26/12 Consensus. FEP variation changed to reference FEP Medical Policy Manual MP-1.01.16 Negative Pressure Wound Therapy in the Outpatient Setting.
	CAC 9/24/13 Minor. Adopting BCBSA for the following changes. • Changed Vacuum Assisted Wound Closure (VAWCD) to negative pressure wound therapy (NPWT). • Added the term "powered" to existing policy statements to specify criteria is for the powered NPWT.

POLICY TITLE	NEGATIVE PRESSURE WOUND THERAPY IN THE OUTPATIENT SETTING
POLICY NUMBER	MP-4.004

	• Added statement indicating coverage for non-powered NPWT is investigational. Previously silent on non-powered VAWCD. • Added description for chronic wounds as > 90 days • Added medically necessary indication for Non-healing wounds despite optimal wound care (at least 30 days) in patients with underlying clinical conditions which are known to negatively impact wound healing. • Expanded objective improvements of wound healing to 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. • BCBSA Description/Background adopted. • Added definition of comprehensive wound management program. • Deleted additional description of wound care for specific types of wounds. • Deleted statement indicating The VAWCD may be considered medically necessary in the presence of a fistula, except to an organ or body cavity within the vicinity of the wound. • Added rationale section • Added policy guidelines which indicate the following -- Contraindications to the use of NPWT systems include the following conditions as noted by a November 2009 FDA alert: necrotic tissue with eschar, untreated osteomyelitis, nonenteric and unexplored fistulas, malignancy in the wound, exposed nerve, exposed anastomotic site, and exposed organ. • Deleted 2 statements related to earlier initiation of therapy. • Deleted the following statement "Use of a VAWCD may be considered **medically necessary** at the time of hospital discharge for the specific diagnoses listed above, and for similar surgical wounds if wound care was begun in the hospital. It is not required that a patient be homebound to receive nursing services in the patient's home for wound care using a VAWD." Administrative code review completed.
	CAC 9/30/14 Consensus review. Rationale and references updated. No changes to the policy statements.
	01/2015-New 2015 CPT code added to the policy.
	CAC 9/29/15 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed**.** **04/04/16**- admin add A6550
	CAC 11/29/16 Consensus. No change to policy statements. References and rationale updated. Variation reformatting. Coding reviewed.
	Admin update 1/17/18: Medicare variations removed from Commercial Policies effective 1/1/18.

POLICY TITLE	NEGATIVE PRESSURE WOUND THERAPY IN THE OUTPATIENT SETTING
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	11/14/17 Minor revision. Policy statement revisions: • Chronic stage III or IV pressure ulcers further described as > 30 days. • NPWT not reasonable and necessary criteria added. • Added statement that NPWT may be considered medically necessary when continuation of treatment is ordered beyond discharge to the home setting. • Length of coverage criteria added. Cross-Reference, Description/Background, Rationale and Reference sections updated. Coding updated. Effective 6/1/18.
	7/17/18 Consensus review. No change to policy statements. Rationale condensed. References updated.
	10/1/18 Update: Removed deleted ICD-10 codes and added new ICD-10 codes effective 10/1/18.

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