MASSACHUSETTS

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Medical Policy

Negative Pressure Wound Therapy in the Outpatient Setting

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Policy Number: 543

BCBSA Reference Number: N/A

Related Policies 543

- Orthopedic Applications of Platelet-Rich Plasma, #737
- Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions, #507
- Electrostimulation and Electromagnetic Therapy for Treating Wounds, #655
- Noncontact Ultrasound Treatment for Wounds, #657
- Bio-Engineered Skin and Soft Tissue Substitutes, #663

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Initiation of a powered negative pressure wound therapy (NPWT) system is considered **MEDICALLY NECESSARY** when the individual meets **ALL** of the criteria (1, 2, 3, 4 and 5) below:[1]

1. A complete wound care program, which meets **ALL** of the requirements below, has been tried:
   - Documentation in the individual's medical record of evaluation, care, and wound measurements by a licensed medical professional; **AND**
   - Application of dressings to maintain a moist environment; **AND**
   - Debridement of necrotic tissue if present; **AND**
   - Evaluation of and provision for adequate nutritional status; **AND**
   - Underlying medical conditions (e.g., diabetes, venous insufficiency) are being appropriately managed; **AND**
2. An eligible condition is documented (individual must meet one or more of the following):
   - Stage III or IV pressure ulcers (see key terms below) at initiation of vacuum assisted wound therapy, in individuals who meet **ALL** of the following:
     - The individual has been appropriately turned and positioned; **AND**
     - The individual has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (no special support surface is required for ulcers not located on the trunk or pelvis); **AND**
     - The individual's moisture and incontinence have been appropriately managed, **OR**
   - Neuropathic ulcers in individuals who meet BOTH of the following:

    - The individual has been on a comprehensive diabetic management program; **AND**
    - Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **OR**
  - Ulcers related to venous or arterial insufficiency, in individuals who meet ALL of the following:
    - Compression bandages and/or garments have been consistently applied; **AND**
    - Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **AND**
    - For initiation of therapy in the home setting, presence of the ulcer for at least 30 days; **OR**
  - Dehisced wounds or wound with exposed hardware or bone; **OR**
  - Post sternotomy wound infection or mediastinitis; **OR**
  - Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment; **OR**
  - Skin graft success is questionable and hospital admissions will be avoided (coverage is provided for 5 days); **OR**
  - Wounds with massive exudate/transudate where normal dressings fill up quickly and macerate the wound
3. The wound to be treated is free from all of the following absolute contraindications to vacuum assisted wound therapy:
   - Exposed anastomotic site; **OR**
   - Exposed nerves; **OR**
   - Exposed organs; **OR**
   - Exposed vasculature; **OR**
   - Malignancy in the wound; **OR**
   - Necrotic tissue with eschar present; **OR**
   - Non-enteric and unexplored fistulas; **OR**
   - Untreated osteomyelitis, **OR**
   - Macroscopic contamination.
4. The powered negative pressure wound therapy (NPWT) system is being used as an adjunct therapy or as an alternative to surgery, **AND**
5. The medical record documents that the patient is willing and able to comply with using continuous or intermittent V.A.C. application 22 of 24 hours per day.

Continued use of electrically powered vacuum assisted wound therapy is considered **MEDICALLY NECESSARY** when:

- The initial trial has resulted in documented objective improvements in the wound, **AND**
- Weekly assessment of the wound's dimensions and characteristics by a licensed health care professional is documented; **AND**
- Documentation of progressive wound healing is demonstrated.

Continued use of electrically powered vacuum assisted wound therapy is considered **NOT MEDICALLY NECESSARY** when the continuation of treatment criteria above have not been met.

Electrically powered vacuum assisted wound therapy is considered **INVESTIGATIONAL** for all other applications not meeting the medical necessity criteria above, including when any absolute contraindications to vacuum assisted wound therapy are present.

Non-electrically powered vacuum assisted wound therapy (for example, the SNaP™ Wound Care Device) is considered **INVESTIGATIONAL**.

Portable, battery powered, single use (disposable) vacuum assisted wound therapy devices (for example, the PICO™ Single Use Negative Pressure Wound Therapy System or the V.A.C.Via™ Negative Pressure Wound Therapy System) are considered **INVESTIGATIONAL** for all conditions.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO	Prior authorization is **required**.

Requesting Prior Authorization Using Authorization Manager

Providers will need to use Authorization Manager to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the service request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

Authorization Manager Resources

Refer to our Authorization Manager page for tips, guides, and video demonstrations.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

The following CPT codes require prior authorization for Commercial Managed Care (HMO/POS) and Commercial PPO:

CPT Codes

CPT codes:	Code Description
97605	Negative pressure wound therapy (e.g., vacuum-assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97606	Negative pressure wound therapy (e.g., vacuum-assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

The following HCPCS codes do not require prior authorization:

HCPCS Codes

HCPCS codes:	Code 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

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters

HCPCS Codes

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

Description

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 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 (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.

Negative pressure wound therapy (NPWT) 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 negative pressure wound therapy (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.

Policy History

Date	Action
9/2023	Policy clarified to include prior authorization requests using Authorization Manager.
3/2023	Annual policy review. Not medically necessary language changed to Investigational; other minor editorial refinements to policy statements; intent unchanged.
6/2022	Prior authorization information clarified for PPO plans. Effective 6/1/2022.
6/2021	Clarified authorization statement
4/2021	Annual policy review. Description, summary and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
3/2020	Annual policy review. Description, summary and references updated. Policy statements unchanged.
3/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
2/2018	Annual policy review. New references added.
2/2017	Annual policy review. New references added.
3/2016	Annual policy review. New references added.
3/2015	Annual policy review. New references added. Clarified coding information.
1/2015	Clarified coding information.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
4/2014	Annual policy review. New references added.
3/2014	Coding information clarified.
2/1/2013	Annual policy review. No change in medical policy statement.
2/1/2013	New policy describing ongoing coverage and non-coverage statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion