Medical Policy
Negative Pressure Wound Therapy in the Outpatient Setting

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Policy Number: 543
BCBSA Reference Number: N/A
NCD/LCD: N/A; See Negative Pressure Wound Therapy Interpretive Guidelines

Related Policies
- 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
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. 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):
   A. 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:
      i. The individual has been appropriately turned and positioned; AND
      ii. 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
      iii. The individual’s moisture and incontinence have been appropriately managed, OR
   B. Neuropathic ulcers in individuals who meet BOTH of the following:
i. The individual has been on a comprehensive diabetic management program; **AND**

ii. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **OR**

C. Ulcers related to venous or arterial insufficiency, in individuals who meet ALL of the following:

   i. Compression bandages and/or garments have been consistently applied; **AND**

   ii. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **AND**

   iii. For initiation of therapy in the home setting, presence of the ulcer for at least 30 days; **OR**

D. Dehisced wounds or wound with exposed hardware or bone; **OR**

E. Post sternotomy wound infection or mediastinitis; **OR**

F. Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment; **OR**

G. Skin graft success is questionable and hospital admissions will be avoided (coverage is provided for 5 days); **OR**

H. 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:

   A. Exposed anastomotic site; **OR**

   B. Exposed nerves; **OR**

   C. Exposed organs; **OR**

   D. Exposed vasculature; **OR**

   E. Malignancy in the wound; **OR**

   F. Necrotic tissue with eschar present; **OR**

   G. Non-enteric and unexplored fistulas; **OR**

   H. Untreated osteomyelitis; **OR**

   I. 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** and **NOT MEDICALLY NECESSARY** 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** and **NOT MEDICALLY NECESSARY** for all conditions.

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** and **NOT MEDICALLY NECESSARY** for all conditions.
Medicare HMO Blue™ and Medicare PPO Blue™ Members

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the links below.

Negative Pressure Wound Therapy Interpretive Guidelines March 2012

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required. Yes indicates that prior authorization is required. No indicates that prior authorization is not required.

N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Yes</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO Blue™</td>
<td>Yes</td>
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<tr>
<td>Medicare PPO Blue™</td>
<td>No</td>
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</tbody>
</table>

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:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>97605</td>
<td>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</td>
</tr>
<tr>
<td>97606</td>
<td>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</td>
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HCPCS Codes

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<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>A6550</td>
<td>Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories</td>
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<tr>
<td>A7000</td>
<td>Canister, disposable, used with suction pump, each</td>
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<tr>
<td>A7001</td>
<td>Canister, nondisposable, used with suction pump, each</td>
</tr>
<tr>
<td>E2402</td>
<td>Negative pressure wound therapy electrical pump, stationary or portable</td>
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</tbody>
</table>
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:

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<tr>
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<th>Code Description</th>
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<tr>
<td>97607</td>
<td>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</td>
</tr>
<tr>
<td>97608</td>
<td>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</td>
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HCPCS Codes

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<tr>
<th>HCPCS codes:</th>
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<tr>
<td>A9272</td>
<td>Mechanical wound suction, disposable, includes dressing and all accessories and components, each</td>
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Description

The management and treatment of chronic wounds, including decubitus ulcers, remains challenging. Most chronic wounds will heal only if the underlying cause (ie, venous stasis, pressure, infection) 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 (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) 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 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 (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 evidence review is use of NPWT in the outpatient setting.
Summary

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.

The evidence for NPWT in individuals who have chronic pressure ulcers includes randomized controlled trials (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 patients were treated in an inpatient setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for NPWT in individuals who have chronic wounds and comorbidities affecting wound healing includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbidity, quality of life, and treatment-related morbidity. RCTs have been published on diabetic lower-extremity ulcers of unknown duration, amputation wounds, and nonhealing lower-extremity ulcers due to venous insufficiency. The largest body of evidence is for foot ulcers in patients who have diabetes, showing a higher rate of wound healing and fewer amputations with NPWT. A single RCT in patients with nonhealing leg ulcers who were treated with skin grafts found a faster rate of healing with NPWT. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for NPWT in individuals who have traumatic or surgical wounds (acute or nonhealing) includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbidity, 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 for 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 in any wound outcome measure. However, 1 small RCT suggests that prophylactic NPWT may reduce the number of dressing changes and pain when used in an outpatient setting. Additional study in a larger sample is needed to evaluate this outcome measure. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for single-use portable NPWT systems in individuals who have any wound type includes an RCT of the nonpowered Smart Negative Pressure (SNaP®) Wound Care System and a pseudorandomized study of the PrevenaTM Incision Management System. Relevant outcomes are symptoms, change in disease status, morbidity, quality of life, and treatment-related morbidity. One study with the SNaP non-powered Wound Care System showed non-inferiority to a V.A.C. device. However, interpretation of this study is limited by a high loss to follow-up and lack of a control group treated with dressings. RCTs with small numbers of patients using portable electric NPWT systems are insufficient to draw conclusions about its impact on net health outcome, both for the device itself and in comparison with current care. Well-designed comparative studies with larger numbers of patients are needed. Results from larger RCTs are expected. The evidence is insufficient to determine the effects of the technology on health outcomes.

Overall, the evidence from comparative clinical trials demonstrated that 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 non-healing 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.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>2/2017</td>
<td>New references added.</td>
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<tr>
<td>1/2015</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>3/2014</td>
<td>Coding information clarified.</td>
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<tr>
<td>2/1/2013</td>
<td>BCBSA National medical policy review. No change in medical policy statement.</td>
</tr>
<tr>
<td>2/1/2013</td>
<td>New policy describing ongoing coverage and non-coverage statements.</td>
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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

References


Endnotes

1 Based on expert opinion