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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Negative pressure wound therapy consists of the use of a negative pressure or suction device to reduce infection and promote healing in wounds of various etiologies.

Background

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 nonpowered (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.

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: V.A.C.[®] (Negative pressure therapy Assisted Closure[®]) Therapy™ (Kinetic Concepts Inc.); Versatile 1™ Wound Negative pressure therapy System (Blue Sky Medical), RENASYS™ EZ and RENASYS GO systems (the latter is a portable system) (Smith&Nephew) and the PICO™ Single-Use Negative Pressure Wound Therapy System (Smith&Nephew).

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. It received 510(k) marketing clearance from FDA in 2009 (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, 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 that had been associated with NPWT systems. An updated alert was issued in February 2011. (Available online at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.htm>.)

Related Protocols

Skin Contact Monochromatic Infrared Energy as a Technique to Treat Cutaneous Ulcers, Diabetic Neuropathy, and Miscellaneous Musculoskeletal Conditions

Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions

Bio-Engineered Skin and Soft Tissue Substitutes

Policy (Formerly Corporate Medical Guideline)

Initiation of Powered Negative Pressure Wound Therapy (NPWT):

An initial therapeutic trial of not less than two 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 (> 90 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.)

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 two-week therapeutic trial or a subsequent treatment period if the treatment has resulted in documented objective improvements in the wound. 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.

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.

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

Use of non-powered NPWT systems for the treatment of acute or chronic wounds is investigational.

Policy Guideline

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.

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.

Continuation of healing during use of the NPWT system should be monitored on a frequency 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 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.

The focus of these policy statements and guidelines is for use of NPWT in the outpatient setting.

Medicare Advantage

For Medicare Advantage an NPWT pump and supplies are **medically necessary** when the following criterion is met:

The patient has a chronic Stage III or IV pressure ulcer*, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

1. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:
 - a. Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional,

- b. Application of dressings to maintain a moist wound environment,
 - c. Debridement of necrotic tissue if present, and
 - d. Evaluation of and provision for adequate nutritional status.
2. For Stage III or IV pressure ulcers:
 - a. The patient has been appropriately turned and positioned, and
 - b. The patient has used a support surface for pressure ulcers on the posterior trunk or pelvis, and
 - c. The patient's moisture and incontinence have been appropriately managed.
 3. For neuropathic (for example, diabetic) ulcers:
 - a. The patient has been on a comprehensive diabetic management program, and
 - b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.
 4. For venous insufficiency ulcers:
 - a. Compression bandages and/or garments have been consistently applied, and
 - b. Leg elevation and ambulation have been encouraged.
 5. For ulcers and wounds that met the following criteria in the inpatient setting and need treatment beyond discharge to the home setting:
 - a. Any of the ulcer or wounds described above where the treatments described above had been tried or considered and ruled-out and NPWT was determined the appropriate treatment; or
 - b. Complications of a surgically created wound (for example dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, where other medical conditions of the patient might impede healing times if just topical wound treatments were used).

If criterion above is not met, the NPWT pump and supplies are **not medically necessary**.

NPWT pumps need to be capable of accommodating more than one wound dressing set in the case when the patient has multiple wounds. In other words, it would be **not medically necessary** for more than one NPWT pump at a time.

An NPWT pump and supplies are **not medically 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;
- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound; and
- The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

Continued medical appropriateness:

For wounds and ulcers described above, once placed on an NPWT pump and supplies, in order to continue to be considered **medically necessary** a licensed medical professional must do the following:

1. On a regular basis:
 - a. directly assess the wound(s) being treated with the NPWT pump, and
 - b. supervise or directly perform the NPWT dressing changes, and
2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If these criteria are not fulfilled, continued coverage of the NPWT pump is **not medically necessary**.

An NPWT pump and supplies are **not medically necessary** with any of the following, whichever occurs earliest:

- A) Continued medical appropriateness criteria are no longer met,
- B) In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
- C) Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound,
- D) Four (4) months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound,
- E) Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

It is usually **not medically necessary** to need more than 15 dressing kits per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.

It is usually **not medically necessary** to need more than 10 canister sets per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). For high volume exudative wounds, it is **medically necessary** to only use a stationary pump with the largest capacity canister.

*The staging of pressure ulcers used in this Protocol is as follows:

Suspected deep Tissue Injury: Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

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 are 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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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