Medical Coverage Policy | Disposable Negative Pressure Wound Therapy

EFFECTIVE DATE: 07|01|2017
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OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Medicare Advantage Plans and Commercial Products
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of (powered or nonpowered) disposable single-use NPWT system devices for the treatment of acute or chronic wounds including but not limited to diabetic, venous, surgical, and traumatic wounds, is not covered, as they do not meet the durable medical equipment (DME) benefit durability requirement.

Commercial Products
The use of (powered or nonpowered) disposable single-use NPWT system devices for the treatment of acute or chronic wounds including but not limited to diabetic, venous, surgical, and traumatic wounds, is considered not medically necessary, as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
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.

Single-use 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: PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew), SNaP® Wound Care System and the Prevena™ Incision Management System (KCI) which is designed specifically for closed surgical incisions. PICO is a portable single-use NPWT system that comes with 2 sterile dressings and has a lifespan of 7 to 14 days.

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.

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) pathway (K081406) and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers.

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 DFUs, but was not duplicated in the per protocol population due to a high number of exclusions. One study of the Smart Negative Pressure nonpowered Wound Care System (SNaP) 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 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 a 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 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. 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.

CODING

The following code is not medically necessary for Commercial Products and is not covered for Medicare Advantage Plans, as it does not meet the DME benefit durability requirement:

A9272 Wound suction, disposable, includes dressing, all accessories and components, any type, each

The following codes are not medically necessary for Commercial Products and are covered for Medicare Advantage Plans.

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

RELATED POLICIES

Prior Authorization via Web-Based Tool for Durable Medical Equipment (DME)

PUBLISHED

Provider Update, May 2021
Provider Update, April 2020
Provider Update, July 2019
Provider Update, August 2018
Provider Update, May 2017

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