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OVERVIEW

Disposable, non-powered mechanical negative pressure wound therapy (NPWT) or single-use, non-electrically powered negative pressure wound therapy have been proposed for the treatment of smaller wounds. These devices can be used in the hospital, outpatient, and/or home settings.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

The use of non-powered NPWT system devices (non-electrically powered (mechanical); single use (disposable) battery operated) for the treatment of acute or chronic wounds is not covered, as they do not meet the durable medical equipment (DME) benefit durability requirement.

Commercial Products

The use of non-powered NPWT system devices (non-electrically powered (mechanical); single use (disposable) battery operated) for the treatment of acute or chronic 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

Negative pressure wound therapy (NPWT) devices can be classified as either powered (i.e., requiring an external power source), or non-powered (i.e., mechanical). The focus of this policy is on disposable, non-powered or battery operated NPWT.

A number of non-powered negative pressure wound therapy (single use) portable devices have entered the market for use in the outpatient setting. Some of these non-powered negative pressure wound therapy (single use) portable devices are designed specifically for surgical incisions.

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 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. 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.

Conventional NPWT using a powered negative pressure wound therapy system can be bulky and intrusive for patients who are ambulatory and active. Disposable non-powered NPWT (mechanical) or single use (disposable) non-powered (battery operated) negative pressure wound therapy have been proposed for the treatment of small to medium sized, slow to heal wounds and also for the management of surgical incisions. The goal of these devices is to make it easier to use by both the clinicians and patients. Specifically, the device should be one that clinicians can take off the shelf like any other wound care dressing, it is quick and easy to apply, and the patients can wear under their clothes and will not impinge on their normal activities. The idea was to make it practical and cost effective, allowing more patients to benefit from NPWT in the outpatient/home setting.

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) 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.

The following are non-powered, single use NPWT systems:

SNaP® Wound Care System

The Smart Negative Pressure (SNaP) Wound Care System (Spiracur, Sunnyvale, CA) is a disposable, ultraportable NPWT device that does not require an electrically-or-battery powered pump. The SNaP System is a mechanically-powered NPWT system comprising spring technology that reduces air density within an enclosure in a controlled manner. The specialized springs equilibrate even in the presence of exudate so that a constant controlled amount of negative pressure is delivered to the wound bed. Because there is no electrical pump, operation of the SNaP System is completely silent, and it is small enough to be worn on a patient's leg, arm or belt and hidden underneath clothing. The (SNaP) Wound Care System consists of three basic elements; the cartridge with activation/reset key, the hydrocolloid dressing layer, and the strap with attachment clip.

PICO™ Single Use Negative Pressure Wound Therapy

PICO™ Single Use Negative Pressure Wound Therapy (Smith and Nephew, St. Petersburg, FL) is a pocket sized disposable single use negative pressure wound therapy system. The PICO™ device consists of a small, portable pump with a lifespan of up to 7 days. The PICO™ pump generates an effective negative pressure of 80mmHg yet is small enough to fit discretely into a pocket.

V.A.C.VIA™ Therapy System

V.A.C.Via™ Therapy System (KCI, San Antonio, TX) is a portable single patient use negative pressure wound therapy device that offers 7 days of therapy. Provides dynamic pressure control and continuous negative pressure options of 75mmHg or 125mmHg. When used on closed surgical incisions, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

ciSNAP® Closed Incision System

ciSNAP Closed Incision System (Spiracur, Sunnyvale, CA) is a single use portable, non-powered, disposable negative pressure wound therapy system that is intended for wound management through the removal of small amounts of exudate from surgical incisions that continue to drain following sutured or stapled closure. There is proprietary spring mechanism that generates consistent, even levels of pressure.

Prevena Incision Management System (KCI, San Antonio, TX)

Prevena Incision Management System is a negative pressure wound therapy (NPWT) device designed specifically for management of closed surgical incisions that continue to drain following sutured or stapled closure. The single use system consists of a negative pressure therapy unit, a canister, and dressing. The therapy unit uses three AA batteries to deliver 125 mm Hg of negative pressure to the incision site and has an eight day life. The therapy unit has alerts for leaks, low battery, maximum capacity and system errors.

For individuals who have any wound type (acute or nonhealing) who receive portable single-use outpatient NPWT, the evidence is insufficient to determine the effects of the technology on health outcomes. The available studies are insufficient to draw conclusions about the efficacy of the service. Therefore use of non-powered NPWT systems for the treatment of acute or chronic wounds is considered not medically necessary.

CODING

The following code is not medically necessary for Commercial Products and is not covered for BlueCHiP for Medicare, 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 BlueCHiP for Medicare.

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

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

PUBLISHED

Provider Update, August 2018

Provider Update, May 2017

Provider Update, January 2017

Provider Update, May 2015

Provider Update, January 2015

Provider Update, February 2014

Provider Update, February 2013

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