# Humana

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# **Medical Coverage Policy**

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#### Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. Refer to the <u>CMS website</u>. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

# **Related Medical/Pharmacy Coverage Policies**

None

#### Description

Negative pressure wound therapy (NPWT), also called vacuum assisted wound closure, refers to wound dressing systems that continuously or intermittently apply subatmospheric pressure to the surface of a wound. NPWT is most commonly used in the treatment of acute and chronic wounds such as surgical wounds, various soft tissue injuries or ulcers (eg, diabetic foot, pressure and venous leg). This technique may also be prescribed to promote healing prior to using a flap or skin graft by advancing early healing of the site, thereby preparing the wound bed for surgical reconstruction. NPWT involves the application of a localized vacuum to the wound surface to draw the edges of the wound together. NPWT devices are available as rental (portable) or disposable (single-use) units.

The NPWT device consists of a dressing of gauze and/or open-celled reticulated foam that is placed in the wound. A tube is embedded into the dressing and sealed with an adhesive transparent dressing. Attached to the tube is a vacuum pump which applies negative pressure to the wound. This pressure drains fluid and exudates from the wound to a disposable canister. The intent of this treatment is to help reduce edema,

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improve vascularity and oxygenation of the wound bed, provide a moist environment and help stimulate healthy granulation tissue conducive to rapid wound healing.

Negative pressure wound therapy placement over surgically closed incisions is an alternative to absorbent dressings, gauze and adhesive medical tape (eg, npSIMS, Prevena, Prevena Duo and Prevena Restor Incision Management System). Purportedly intended to promote healing by holding incision sides closed, removing fluid and reducing the incidence of seromas and surgical site infections. (Refer to Coverage Limitations section)

Negative pressure wound therapy with instillation (NPWTi) is the combination of NPWT with timed, intermittent delivery of a topical solution. The fluid reportedly helps to remove wound exudate, slough and bacteria to purportedly promote more rapid healing of the wound. The solution is delivered and remains in the wound for a set amount of time and subsequently removed via NPWT. (Refer to Coverage Limitations section)

Examples of NPWT devices include, but may not be limited to:

#### **Rental (Portable) Units**

- ActiV.A.C. Therapy Unit
- CATALYST
- Invia Liberty NPWT System
- Prospera PRO-I, PRO-II and PRO-III
- RENASYS GO
- SVED Wound Treatment System
- V.A.C. Freedom Therapy Unit

# NPWTi Units (Refer to Coverage Limitations section)

- V.A.C.Ulta NPWTi System
- V.A.C. Veraflo Therapy

# Single-Use, Disposable Units (Refer to Coverage Limitations section)

- Avelle Negative Pressure Wound Therapy System
- Invia Motion NPWT Systems (available in six versions with different run times)
- MyNeWT Negative Pressure Wound System
- Nexa Negative Pressure Wound Therapy System
- NPseal
- npSIMS Negative Pressure Surgical Incision Management System (npSIMS)
- PICO and PICO 7Y Single Use Negative Pressure Wound Therapy Wound System
- Prevena, Prevena Duo and Prevena Restor Incision Management System
- PWD Negative Pressure Wound Therapy System
- SNaP Wound Care System
- UNO Negative Pressure Wound Therapy System
- V.A.C. Via Therapy System

# **Coverage Determination**

Humana members may be eligible under the Plan for the **initiation of a** <u>rental (portable)</u> **NPWT device and 30 days of treatment** when the following criteria are met:

- Absence of <u>contraindications</u>; AND
- Chronic, nonhealing ulcer with lack of improvement greater than 30 days duration despite <u>standard</u> wound therapy and weekly evaluations by an appropriate licensed medical professional with documentation of wound measurements (eg, length, width and depth) AND ONE of the following criteria are met:
  - Chronic neuropathic (diabetic) ulcer:
    - Documentation of hemoglobin A1c (HbA<sub>1c</sub>); AND
    - Individual has been referred to a comprehensive diabetic management program; AND
    - Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; **OR**
  - Chronic <u>stage 3 or stage 4</u> pressure injury:
    - Moisture and incontinence have been addressed; AND
    - Reduction in pressure on the posterior trunk or pelvis injuries have been accomplished with appropriate modalities; AND
    - Turning and repositioning regimens have been performed; OR
  - Chronic venous ulcer:
    - Compression garments/dressings have been consistently applied; AND
    - Leg elevation and ambulation have been encouraged; AND
    - Vascular evaluation and correction of varicosities have been performed; OR
- Adjunct treatment for complications of a surgically created wound (eg, dehiscence, wound with exposed hardware or bone, poststernotomy mediastinitis or postoperative disunion of the abdominal wall); **OR**
- Adjunct treatment of a traumatic wound (eg, preoperative flap or graft, exposed bones and tendons) and a need for accelerated formation of granulation tissue not achievable by other topical wound treatments (eg, the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments)

Humana members may be eligible under the Plan for **the continuation of NPWT treatment for an additional 30 days** for the treatment of wounds when documentation is provided by an appropriate licensed medical professional and **ALL** of the following criteria are met:

- Measurable improvement in the wound (eg, wound dimensions and characteristics), if no surgical debridement has occurred in the last 30 days **OR** since last wound measurement; **AND**
- Provisions are made for adequate nutritional status (normal albumin, prealbumin, protein levels) if abnormal; **AND**
- Underlying medical conditions (eg, diabetes mellitus, venous insufficiency) are being appropriately
  managed (eg, HbA<sub>1c</sub> test should be done quarterly in an individual whose therapy has changed or is not
  meeting glycemic goals<sup>3</sup>)

Coverage for NPWT, if all of the above criteria continue to be met, should last a maximum of 3 months (including both inpatient and outpatient treatment time).

Commercial Plan members: all requests for NPWT beyond 3 consecutive months, require review by a medical director.

Coverage for NPWT will be discontinued at the time ANY of the following occur:

- Equipment or supplies are no longer being used (by individual discretion or the physician's order); OR
- Individual cannot tolerate the use of NPWT; OR
- No measurable degree of wound healing has occurred over the prior month (unless documentation shows surgical debridement as the cause for larger measurements); **OR**
- Uniform granulation tissue has been obtained; OR
- Wound depth can no longer accommodate the sponge as reticulated foam dressing should not overlap onto intact skin

#### Coverage for NPWT supplies will be provided as follows:

- Up to a maximum of 15 dressing kits (A6550) per month
- Up to a maximum of 10 canister sets (A7000) per month

# **Coverage Limitations**

Humana members may **NOT** be eligible under the Plan for **NPWT devices** in wounds that have responded to standard therapeutic measures **OR** for individuals with the following contraindications:

- Exposed vital organs; OR
- Fistulas to organs or body cavities; OR
- Malignancy in the wound; **OR**
- Necrotic tissue with eschar; OR
- Placement over exposed arteries or veins; OR
- Placement over exposed nerves; OR
- Presence of exposed anastomotic sites (located at the site of the surgical connection of two tubular structures); **OR**
- Untreated osteomyelitis

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **NPWT devices** in wounds that have responded to standard therapeutic measures **OR** for individuals with the following risk factors:

- Active bleeding; **OR**
- Adhesive allergies; OR
- Fragile skin due to age, chronic corticosteroid use or collagen vascular disorder; OR
- Inadequate wound hemostasis; OR
- Inadequately debrided wounds; OR
- Untreated cellulitis; **OR**
- Use of anticoagulation (eg, apixaban [Eliquis], dabigatran [Pradaxa], edoxaban [Savaysa], enoxaparin [Lovenox], fondaparinux [Arixtra], heparin, rivaroxaban [Xarelto], warfarin [Coumadin]); but <u>excluding</u> <u>antiplatelet agents</u> (eg, aspirin, clopidogrel [Plavix], dipyridamole [Persantine], dipyridamole/aspirin [Aggrenox], eptifibatide [Integrilin], prasugrel [Effient], ticagrelor [Brilinta], ticlopidine [Ticlid])

These are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **NPWT devices** for any indications other than those listed above including, but may not be limited to, the following:

- <u>NPWTi</u>; OR
- Placement over surgically closed incisions; OR
- Single use, disposable NPWT devices

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

# **Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), 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	Not Covered if used to report any device outlined in Coverage Limitations section
97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	Not Covered if used to report any device outlined in Coverage Limitations section
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	Not Covered

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	Not Covered
CPT <sup>®</sup> Category III Code(s)	Description	Comments
No code(s) ic	lentified	
HCPCS Code(s)	Description	Comments
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories	Not Covered if used to report any device outlined in Coverage Limitations section
A7000	Canister, disposable, used with suction pump, each	
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each	Not Covered
E2402	Negative pressure wound therapy electrical pump, stationary or portable	Not Covered if used to report any device outlined in Coverage Limitations section
K0743	Suction pump, home model, portable, for use on wounds	Not Covered if used to report any device outlined in Coverage Limitations section
К0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq in or less	Not Covered if used to report any device outlined in Coverage Limitations section
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	Not Covered if used to report any device outlined in Coverage Limitations section

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# Appendix

### Appendix A

#### Standard wound therapy based on the specific type of wound includes:

- Appropriate offloading; AND
- Assessment of an individual's vascular status and correction of any amenable vascular problems for arterial and/or venous ulcers; **AND**
- Comprehensive patient assessment (history, exam, Ankle-Brachial Index [ABI]) and diagnostic tests as indicated) and implemented treatment plan; **AND**
- Compression garments/dressings have been consistently applied for venous ulcers; AND
- Frequent repositioning of an individual with pressure injuries (usually every 2 hours); AND
- Improvement of glucose control with documented (within the past 90 days) glycosylated hemoglobin level (HbA1c) less than 9.0% or blood glucose records demonstrating efforts to sustain blood sugar less than 200 mg/dL; **AND**
- Individual with venous leg ulcer (VLU) assessment of clinical history (prior ulcers, thrombosis risks), physical exam (edema, skin changes), ABI, diagnostic testing to verify superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis; **AND**
- Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings (eg, alginate, films, foams, hydrocolloid, hydrogels that provide a moist wound environment); **AND**
- Necessary treatment to resolve any infection that may be present (eg, antibiotics, debridement of devitalized tissue, surgical management of osteomyelitis); **AND**
- Optimization of nutritional status with documented prealbumin level greater than 20 mg/dL or albumin level greater than 3.4 g/dL

# Appendix B

Pressure injury/wound staging classifications<sup>38</sup>:

Stage 1	Nonblanchable erythema of intact skin – Intact skin with a localized area of
Pressure Injury	nonblanchable erythema which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.
Stage 2 Pressure Injury	Partial thickness skin loss with exposed dermis – The wound bed is viable, pink or red, moist and may also present as an intact or ruptured serum filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARSI) or traumatic wounds (skin tears, burns, abrasions).
Stage 3 Pressure Injury	<b>Full thickness skin loss</b> – Adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed.
Stage 4 Pressure Injury	<b>Full-thickness skin and tissue loss</b> – Full-thickness skin and tissue loss with exposed or directly palpable bone, cartilage, fascia, ligament, muscle or tendon in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location.
Unstageable Pressure Injury	<b>Obscured full-thickness skin and tissue loss</b> – The extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (dry, adherent and intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.
Deep Tissue Pressure Injury (DTPI)	Persistent nonblanchable deep red, maroon or purple discoloration – Intact or nonintact skin with localized area of persistent nonblanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury or may resolve without tissue loss. If fascia, granulation tissues, muscle, necrotic tissues, subcutaneous tissues or other underlying structures are visible, this

	indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic or dermatologic conditions.
Medical Device Related Pressure Injury	Injury resulting from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.
Mucosal Membrane Pressure Injury	Injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these injuries cannot be staged.

# Change Summary

- 07/25/2024 Annual Review, No Coverage Change.