Negative Pressure Wound Therapy (NPWT) in the Outpatient Setting

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Page Number(s):	1 of 16

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the Durable Medical Equipment (DME) benefit of the Company's Medicaid products for medically necessary electrically powered negative pressure, vacuum assisted wound closure therapy.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Exudate (drainage) – Interstitial fluid produced by the body in response to tissue damage. Exudate production is essential for moist wound healing. Normally, the production reduces overtime but there are wounds that do not heal as expected, which will produce excessive exudate or no exudate. A wound should not have extreme wetness or dryness in the healing process.

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently serves Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan and Health Plan Plus members.

Licensed Health Care Professional – For the purposes of this policy, a licensed health care professional is a physician, physician assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving vacuum assisted wound closure therapy.

Vacuum Assisted Wound Closure Device – A type of medical therapy that involves the use of suction (negative pressure) underneath airtight wound dressings to promote the healing of opens wounds that have been resistant to previous treatments. Device is also known as: Wound VAC, negative pressure wound therapy (NPWT), vacuum assisted wound closure, sealed surface wound suction (SSS), sub atmospheric pressure therapy or dressing (SWT), foam suction dressing and vacuum pack technique (VPT), vacuum sealing technique (VST), incisional negative pressure wound therapy (INPWT), closed incision management (CIM) topical negative pressure therapy (TNP) and prophylactic negative pressure wound therapy (PNPWT).

Wound Healing – The improvement occurring in either surface area (length x width) or the depth of the wound.

PROCEDURES

Prior authorization is required.

Negative Pressure Wound Therapy may be considered medically necessary when the following criteria are met for all wound types:

A. The patient must be age 12 and older; AND
B. A complete wound care program has been tried which includes all of the following:
    1. Documentation in the medical record by a licensed medical professional on the current and previous wound care management and wound healing progress; AND
    2. The patient has a complex wound where size, depth, location, complications, exudate amount, etiology and/or other specific factors support non-feasibility of healing with moist topical dressing; AND
    3. Wound care physician notes contain an initial wound measurement followed by measurements at a minimum of once a month. Documentation must show the progress of the healing wound and anticipated duration of vacuum assisted wound therapy (e.g., degree of wound healing required); AND
    4. Controlling of comorbid conditions diabetes, nutritional issues, and pressure relief at wound site (**Note:** See Contraindications and Precautions Below); AND
    5. Operative note or wound care notes if requests are for treatment in surgical and/or traumatic wounds; AND
    6. If the initiation of NPWT occurred during an inpatient stay, the initial date of service is to be documented.
C. Use of vacuum assisted wound devices in the outpatient setting are considered medically necessary appropriate for the following conditions:
    1. Chronic Stage III or IV pressure ulcers (>30 days) that have failed to heal despite optimal wound care when:
        a. Standard dressings cannot be maintained due to anatomic factors; AND
        b. The patient's incontinence and/or moisture issues have been appropriately managed; AND
        c. There has been use of group 2 or 3 support surface for pressure ulcers on the trunk or pelvis; OR
    2. Neuropathic (e.g., diabetic) ulcers
        a. The patient has been actively involved in a comprehensive diabetic management; AND
        b. Pressure on a foot ulcer has been appropriately reduced using medically appropriate modalities; OR
    3. Venous or arterial insufficiency ulcers or chronic ulcers of mixed etiology
        a. Compression bandages OR garments have been applied appropriately; AND
        b. Elevating the affected extremity has been maintained while the patient is sedentary; AND

c. Ambulation/leg exercises that promote circulation have been encouraged and utilized; AND
d. For initiation of vacuum assist wound device in the home setting, the ulcer must have been present for at least 30 days; OR

4. Traumatic or surgical wounds (i.e., preoperative flap or graft, exposed bones, tendons, or vessels) that need accelerated formation of granulation tissue; not achievable by other topical wound treatments (e.g., comorbid conditions of the patient that will hamper appropriate healing with other topical wound treatments) and no contraindications to negative pressure wound therapy. The following traumatic or surgical wound conditions include:
   a. Wounds refractory to standard wound regimens; OR
   b. Burns; OR
   c. Complications of surgically created wounds (i.e., dehiscence, post-sternotomy disunion with exposed sternal bone, post-sternotomy mediastinitis, or post-operative disunion of the abdominal wall) which may include the use of skin grafts to assist in wound closure.

Note: The individual NPWT pump is able to accommodate more than one wound dressing set for multiple wounds on a patient. If more than one NPWT pump is utilized on the patient during the same period, the service will be denied as not medically necessary.

The following supplies are medically necessary for negative pressure wound therapy, including:

A. Wound care sets will be limited to up to 15 dressing kits per wound, per month. Documentation must be provided to support the medical necessity for requests in excess of limitation.
B. Canister sets will be limited to 10 per month in most cases. Documentation must be provided showing evidence that a large volume of drainage exists.
   - Example: Documentation must show an exudate amount greater than 90 ml of exudate per day.

Note: Vacuum assist devices are capable of accommodating more than one wound dressing set for multiple wounds on a patient. Therefore coverage for more than one pump per patient for the same time period will be considered noncovered and not medically necessary.

CONTINUATION OF SERVICES

A. Continuation of the powered vacuum assist wound device is considered medically necessary following an initial two week therapeutic trial or a subsequent period if the treatment has resulted in documented improvements of the wound; AND
B. Coverage for the medically necessary powered vacuum assist wound device will end when the treating physician reports adequate wound healing has occurred to the degree where the device may be discontinued; AND
C. There must be documentation by the wound care physician regarding wound healing. Documentation of wound progress measurements include:
   1. Decrease wound size (length, width, depth, undermining, tunneling); AND
   2. Increased granulation tissue; AND
   3. Increase epithelialization; AND
   4. Decreased wound odor; AND
   5. Decreased wound pain; AND
   6. Decreased volumes of exudate; AND
D. Continued use of this therapy should be reviewed against outcome criteria at the beginning of therapy, at each dressing change or, at a minimum of every two weeks and reported on a monthly basis
E. Recent laboratory values do not demonstrate a contraindication exists.

Note: In some circumstances, the use of this treatment modality when initiated in the inpatient setting may not meet the criteria for use in the outpatient setting. A review for medical necessity determination by a Medical Director will be performed.

CONTRAINDICATIONS

The wound being treated must be free of the following absolute contraindications for NPWT:

A. No vacuum assisted wound device has been cleared for use in infant and children. Patient size and weight should be considered when prescribing this device; OR
B. Exposed anastomotic site; OR
C. Exposed nerves; OR
D. Exposed organs; OR
E. Exposed vasculature; OR
F. Malignancy in the wound; OR
G. Necrotic tissue with eschar present; OR
H. Non-enteric and unexplored fistulas; OR
I. Untreated osteomyelitis; OR
J. Severe peripheral arterial disease: Ankle Brachial Pressure Index ≤ 0.5 needs investigation, and if appropriate, revascularization prior to commencement of vacuum assist device; OR

PRECAUTIONS

A. The following factors have been identified as risks to wound healing and should be adequately addressed by the ordering provider:
    1. Active smoking
    2. Obesity
    3. Poorly managed diabetes
    4. Pulmonary disease
    5. Uremia
    6. Ascites
    7. Anemia
    8. Jaundice
    9. Steroid Use

B. Malnourished patients who have not received adequate nutrition/nutritional supplements (e.g., hyperalimentation).
C. Caution should be used for patients with neuropathic or circulatory compromise.
D. Caution should be used towards non-concordant or combative patients.
E. Caution should be used towards patients with infected wounds; they may require more frequent dressing changes.
F. Patients with burns; the devitalized burned tissue must be debrided prior to application of NPWT.
G. Patients with wounds in close proximity to blood vessels, delicate fascia, vital organs or exposed tendons (ensure adequate protection with overlying fascia, tissue or other protective barriers).
H. Bone fragments or sharp edges could puncture protective barriers, vessels, or organs causing injury. Any injury could cause bleeding, which, if uncontrolled results could be fatal.
I. The dressing must be removed if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.
J. The therapy unit is MRI unsafe and should not be taken in the MRI environment; dressings can typically remain on the patient with minimal risk in an MRI environment.

K. Hyperbaric Oxygen Therapy (HBOT): the therapy unit is unsafe in the hyperbaric oxygen chamber and is considered a fire hazard. Care must be taken with the dressing to ensure HBO compatible.
L. Precautions need to be taken in patients receiving long-term anticoagulant therapy, hemophilia and patients with hemoglobinopathies, such as sickle cell.

The NPWT services are not covered and considered not medically necessary when:

A. 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, OR
B. In the judgment of the treating physician the adequate wound healing has occurred to the degree that NPWT may be discontinued and the wound can be anticipated to heal completely with other wound care treatments; OR
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 X width) or depth of the wound; OR
D. The patient/caregiver is unable/unwilling to follow the plan of care; OR
E. The wound has developed evidence of a wound complication contraindicating continued use of the device
F. NPWT that extends beyond four months (this includes NPWT applied in an inpatient setting prior to discharge to the home) is considered not medically necessary and requires Medical Director Review.

Any conditions not listed in criteria above will be considered not medically necessary since the scientific evidence has not been established. Examples of indications not covered include, but are not limited to:

- Use following cardiac surgery not meeting medical necessity criteria above;
- Use following surgical excision of pilonidal sinus and/or recurrent pilonidal disease;
- Use of device as a preventive/prophylactic intervention in patients with surgical wounds, such as a diagnosis of diabetes or obesity as risk factors, ventral hernia repair or post cesarean delivery, post knee arthroplasty or kidney transplantation;
- Use of chemotherapeutic agents in intermittent instillation with NPWT.

Use of a nonpowered vacuum assist device (e.g., SNaP® system) or a battery operated (A9272), disposable system (e.g., PICO™ system) have not been proven in peer-reviewed literature as medically effective and are not medically necessary for the treatment of acute and/or chronic wounds.

If it is determined during the course of treatment for an initial wound that the NPWT system will be applied to additional wounds, all additional wounds must meet the criteria listed in this policy to determine medical necessity.

DME

The negative pressure wound therapy device (E2402) is classified as a DME rental item and may be subject to prior authorization requirements.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE

For the purposes of this policy, the place of service for vacuum assisted wound therapy is in the home setting.

GOVERNING BODIES APPROVAL

On December 20, 2002, the VAC device received premarket approval to include the indication of partial-thickness burns.

On November 13, 2009, the U.S. Food and Drug Administration (FDA) released a Medical Device Alert regarding the use of negative pressure wound therapy systems. The alert notified medical practitioners of possible death or serious complications due to the use of the vacuum assisted wound therapy systems. Per the FDA, it had received reports of six deaths and 77 injuries associated with this device over the two years. Major complications reported included bleeding and infection. The alert provided the recommendations to reduce risks with the device:

A. More careful selection of patients for vacuum assisted wound therapy;
B. Assure that patient monitoring is performed frequently in an appropriate care setting by a trained practitioner. To determine the frequency of monitoring, the provider must consider the patient's condition, including wound status, wound location and comorbidities;
C. Proper training must be obtained prior to prescribing and using the device;
D. Instructions for proper home use of the vacuum assisted wound therapy device to the patient and/or caregiver must be given. This instruction is to include how to use the device, potential complications and their signs and symptoms, and management of complications.

In addition, the FDA listed the following contraindications for vacuum assisted wound therapy:

A. Necrotic tissue with eschar present
B. Untreated osteomyelitis
C. Non-enteric and unexplored fistulas
D. Malignancy (within the wound)
E. Exposed blood vessels, nerves, anastomoses, or organs

To review the full test of the FDA warning, see:
https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm193277.htm

The FDA release an updated Safety Communication on February 24, 2011 regarding major complications of the vacuum assisted wound therapy device. The update addressed the use of the device in the treatment of infants and children. Specifically, 'The safety and effectiveness of vacuum assisted wound therapy devices in newborns, infants and children has not been established at this time and currently, there are no such devices cleared for use in these populations.' The FDA defines a child as 'greater than 2 to 12 years of age' (U.S. FDA Premarket Assessment of Pediatric Medical Devices, 2004).

No NPWT device has been cleared for use in infants and children.

NPD 1000 Negative Pressure Wound Therapy System previously manufactured by Kalypto (Smith and Nephew, St. Petersburg, FL) is a proprietary battery powered negative pressure wound therapy system that absorbs and lock-in small amounts of exudate without a collection container. The dressing drainage capacity is 70 cc. The Centers for Medicare and Medicaid (CMS) has reclassified the device as a portable wound suction pump. The device is marketed as the smallest, lightest and most portable battery operated system available. The device received FDA approval in October 2008.

ELIGIBLE PROCEDURE CODES

CPT code	Description
97605	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment, 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.
97606	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment, including topical application(s), wound assessment, and instruction(s) for ongoing care, per session, total wound(s) surface area greater than 50 square centimeters.
A6550	Wound care set, for negative pressure wound therapy electrical pumps, includes all supplies and accessories.
A7000	Canister, disposable, used with suction pump, each.
A7001	Canister, nondisposable, used with suction pump, each.
E2402	Negative pressure wound therapy electrical pump, stationary or portable.

NONCOVERED PROCEDURE CODES
(These procedure codes will not be reimbursed without Medical Director approval)

CPT code	Description
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each (not covered).
K0743	Suction pump, home model, portable, for use on wounds [for use with NPD 1000).
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 square inches.
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 square inches but less than or equal to 48 square inches.
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 square inches.

COVERED DIAGNOSIS CODES

E08.40	E08.41	E08.42	E08.43	E08.44
E08.49	E08.51	E08.52	E08.59	E08.610
E08.618	E08.620	E08.621	E08.622	E08.628
E08.641	E08.649	E08.65	E08.69	E09.01
E09.10	E09.11	E09.21	E09.22	E09.29
E09.40	E09.41	E09.42	E09.43	E09.44
E09.49	E09.51	E09.52	E09.59	E09.610
E09.618	E09.620	E09.621	E09.622	E09.628

E09.641	E09.649	E09.65	E09.69	E09.8
E09.9	E10.10	E10.11	E10.21	E10.22
E10.29	E10.40	E10.41	E10.42	E10.43
E10.44	E10.49	E10.51	E10.52	E10.59
E10.610	E10.618	E10.620	E10.621	E10.622
E10.628	E10.641	E10.649	E10.65	E10.69
E10.8	E10.9	E11.00	E11.01	E11.21
E11.22	E11.29	E11.40	E11.41	E11.42
E11.42	E11.44	E11.49	E11.51	E11.52
E11.59	E11.610	E11.618	E11.620	E11.621
E11.622	E11.628	E11.641	E11.649	E11.65
E11.69	E11.8	E13.00	E13.01	E13.11
E13.21	E13.22	E13.29	E13.40	E13.41
E13.42	E13.43	E13.44	E13.49	E13.51
E13.52	E13.59	E13.610	E13.618	E13.620
E13.621	E13.622	E13.628	E13.641	E13.649
E13.65	E13.69	E13.8	I70.231	I70.232
I70.233	I70.234	I70.235	I70.238	I70.239
I70.241	I70.242	I70.243	I70.244	I70.245
I70.248	I70.249	I70.25	I70.261	I70.262
I70.263	I70.268	I70.269	I70.331	I70.332
I70.333	I70.334	I70.335	I70.338	I70.339
I70.341	I70.342	I70.343	I70.344	I70.345
I70.348	I70.349	I70.431	I70.432	I70.433
I70.434	I70.435	I70.438	I70.439	I70.441
I70.442	I70.443	I70.444	I70.445	I70.448
I70.449	I70.531	I70.532	I70.533	I70.534
I70.535	I70.538	I70.539	I70.541	I70.542
I70.543	I70.544	I70.545	I70.548	I70.549
I70.631	I70.632	I70.633	I70.634	I70.635
I70.638	I70.639	I70.641	I70.642	I70.643
I70.644	I70.645	I70.648	I70.649	I70.731
I70.732	I70.733	I70.734	I70.735	I70.738
I70.741	I70.742	I70.743	I70.744	I70.745
I70.748	I70.749	I83.001	I83.002	I83.003
I83.004	I83.005	I83.008	I83.009	I83.011
I83.012	I83.013	I83.014	I83.015	I83.018
I83.019	I83.021	I83.022	I83.023	I83.024

I83.025	I83.028	I83.029	I83.201	I83.202
I83.203	I83.204	I83.205	I83.208	I83.209
I83.211	I83.212	I83.213	I83.214	I83.215
I83.218	I83.219	I83.221	I83.222	I83.223
I83.224	I83.225	I83.228	I83.229	I87.2
I87.311	I87.312	I87.313	I87.319	K68.11
L89.003	L89.004	L89.013	L89.014	L89.023
L89.024	L89.103	L89.104	L89.113	L89.114
L89.123	L89.124	L89.133	L89.134	L89.143
L89.144	L89.153	L89.154	L89.203	L89.204
L89.213	L89.214	L89.223	L89.224	L89.303
L89.304	L89.313	L89.314	L89.323	L89.324
L89.43	L89.44	L89.503	L89.504	L89.513
L89.514	L89.523	L89.524	L89.603	L89.604
L89.613	L89.614	L89.623	L89.624	L89.813
L89.814	L89.893	L89.894	L89.93	L89.94
L97.101	L97.102	L97.103	L97.104	L97.109
L97.111	L97.112	L97.113	L97.114	L97.119
L97.121	L97.122	L97.123	L97.124	L97.129
L97.201	L97.202	L97.203	L97.204	L97.209
L97.211	L97.212	L97.213	L97.214	L97.219
L97.221	L97.222	L97.223	L97.224	L97.229
L97.301	L97.302	L97.303	L97.304	L97.309
L97.311	L97.312	L97.313	L97.314	L97.319
L97.321	L97.322	L97.323	L97.324	L97.329
L97.401	L97.402	L97.403	L97.404	L97.409
L97.411	L97.412	L97.413	L97.414	L97.419
L97.421	L97.422	L97.423	L97.424	L97.429
L97.501	L97.502	L97.503	L97.504	L97.509
L97.511	L97.512	L97.513	L97.514	L97.519
L97.521	L97.522	L97.523	L97.524	L97.529
L97.801	L97.802	L97.803	L97.804	L97.809
L97.811	L97.812	L97.813	L97.814	L97.819
L97.821	L97.822	L97.823	L97.824	L97.829
L97.901	L97.902	L97.903	L97.904	L97.909
L97.911	L97.912	L97.913	L97.914	L97.919
L97.921	L97.922	L97.923	L97.924	L97.929
O24.011	O24.012	O24.013	O24.019	O24.02

O24.111	O24.112	O24.113	O24.119	O24.12
O24.311	O24.312	O24.313	O24.319	O24.32
O24.410	O24.414	O24.415	O24.419	O24.420
O24.424	O24.425	O24.429	O24.811	O24.812
O24.813	O24.819	O24.82	O24.912	O24.913
O24.919	O24.92	S41.021A	S41.022A	S41.029A
S41.041A	S41.042A	S41.049A	S41.121A	S41.122A
S41.129A	S41.141A	S41.142A	S41.149A	S51.021A
S51.022A	S51.029A	S51.041A	S51.042A	S51.049A
S51.821A	S51.822A	S51.829A	S51.841A	S51.842A
S51.849A	S61.521A	S61.522A	S61.529A	S61.541A
S61.542A	S61.549A	S71.021A	S71.022A	S71.029A
S71.041A	S71.042A	S71.049A	S71.121A	S71.122A
S71.129A	S71.141A	S71.142A	S71.149A	S81.021A
S81.022A	S81.029A	S81.041A	S81.042A	S81.049A
S81.821A	S81.822A	S81.829A	S81.841A	S81.842A
S81.849A	S91.021A	S91.022A	S91.029A	S91.041A
S91.042A	S91.049A	S91.321A	S91.322A	S91.329A
S91.341A	S91.342A	S91.349A	T81.31XA	T81.32XA
T81.4XXA	T81.89XA			

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Negative pressure wound therapy (NPWT) is a vacuum assisted wound device that has been used in clinical applications for more than five decades. The concept of applying topical negative pressure in the management of wounds emerged in the late 1980s and is increasingly used for a wide variety of wounds. The merits of vacuum assisted wound therapy in the outpatient setting for a variety of wounds such as ulcers related to pressure sores, venous or arterial insufficiency or neuropathy and other wounds have been studied in a number of clinical contexts. NPWT has triggered accelerated wound healing in the outpatient setting which has reduced wound dressing, visits to specialists, and hospitalizations (Lukasz, 2014). An additional positive result of NPWT include significant antibacterial effects by reducing subcutaneous edema (Lukasz, 2014). NPWT devices are classified as either powered (requiring electric power source) or non-powered (mechanical) or battery operated.

It is important to note that these devices are adjunctive therapy and are not intended to replace good basic wound care (i.e., daily wound measurements of dimension and depth, wet dressing applications, necrotic debridement, adequate overall nutrition, and minimization of disease activity of comorbid conditions.

Numerous for NPWT include:

1. Decubitus (pressure) ulcers

2. Neuropathic ulcers
3. Ulcers related to venous or arterial insufficiency
4. Dehisced wounds or wound with exposed hardware or bone
5. Post sternotomy wound infection or mediastinitis, or
6. Complications of a surgically created wound where exhibiting accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment.

Negative pressure wound therapy (NPWT) applies a localized vacuum to draw the edges of the wound together while providing a moist environment conducive to rapid wound healing. The development of negative pressure techniques for wound healing is based on two theories: (1) the removal of excess interstitial fluid (exudate) decreases edema and concentrations of inhibitory factors and increases local blood flow; and (2) stretching and deformation of the tissue by the negative pressure is believed to disturb the extracellular matrix and introduce biochemical responses that promote wound healing.

There are concerns surrounding the quantification of exudate levels within clinical research and day-to-day treatment of wounds (Mulder, 1994). The characteristics of wound exudate vary heavily, in regard to factors such as, wound type, underlying patient conditions, wound bed description, and chronic or acute wound. These influencing factors make it difficult to standardize a specific exudate level for vacuum assisted wound therapy or any other wound therapy (Mulder, 1994). Gerit D. Mulder, the CEO of the Wound Healing Institute in Denver, Colorado produced an exudate output classification for chronic wounds, including:

1. Absent (dry)
2. Minimal (less than 5cc per 24 hours)
3. Moderate (5-10 cc per 24 hours)
4. High (more than 10 cc per 24 hours

According to the Journal of Wound Care (2014), Mulder terminology is familiar in the clinical environment but is not practical in clinical practice due to the numerous factors of wounds. Managing and decreasing exudate production is an important function within NPWT, a licensed clinical professional must assess the fluid quantity and type. A wound vacuum device removes exudate from a wound by applying the negative pressure which can be increased or decreased depending on the needs of the wound.

NPWT systems include a vacuum pump, drainage tubing, and a dressing set. The pump may be stationary or portable, may rely on AC or battery power, allows for regulation of the suction strength, has alarms to indicate loss of suction, and has a replaceable collection canister. The dressing sets may contain either foam or gauze dressing to be placed in the wound and an adhesive film drape for sealing the wound. The drainage tubes come in a variety of configurations depending on the dressings used or wound being treated.

The electric pump applies intermittent or continuous negative pressure to an open cell foam or gauze wound dressing. The dressing evenly distributes pressure to the wound surface. In early stages of healing, fluid is withdrawn by the device, removing inhibitory factors and reducing bacterial counts. In later stages, tensile forces applied to surrounding tissues by the dressing are thought to stimulate cellular proliferation and protein synthesis.

CMS partnered with the AHRQ and commissioned a review of NPWT devices. AHRQ contracted with the ECRI Institute Evidence-based Practice Center to perform the review (AHRQ, 2009). A technology assessment report on NPWT prepared for the AHRQ found that “the systematic reviews of NPWT reveal several important points about this technology. First, all of the systematic reviews noted the lack of high-quality clinical evidence supporting the advantages of NPWT compared to other wound treatments. The lack of high-quality NPWT evidence resulted in many systematic reviewers relying on low-quality retrospective studies to judge the efficacy of this technology. Second, the other systematic reviews found no studies directly comparing different NPWT devices or components have been published. Direct

comparison studies are especially important in determining which dressing approach (foam or gauze) may provide the best potential for wound healing. Third, other systematic reviews concluded that NPWT must be evaluated according to wound type. Wound healing varies according to the type of wound being treated and NPWT benefits described for one wound type cannot be transferred to other wound types. Most wound types have insufficient high-quality NPWT evidence to judge if NPWT is better than standard care for specific wounds. Studies comparing foam to gauze are needed for each wound type before decisions can be made about which systems or components offer significant therapeutic distinctions."

In 2012, the Cochrane Review conducted a systematic review of NPWT to surgical incisions using wound healing as the primary outcome of interest. Unfortunately, assessing the efficacy of NPWT by attempting to determine when a surgical incision is "completely healed" is a difficult endpoint to measure. A more clinically relevant question is how the application of NPWT affects the rate of surgical site complications.

Zhang (2014) conducted a meta-analysis to evaluate the effectiveness and safety of NPWT for diabetic ulcers. Eight qualified studies were identified with a total of 669 patients. Overall, use of the NPWT resulted in a significantly higher proportion of healed diabetic foot ulcers, reduction of ulcer area and shorter time to wound healing. Use of this therapy resulted in fewer major amputations but the rate of minor amputations was not impacted.

NPWT used in a prophylactic role has been reported in primarily observational studies. While there have been a small number of small trials, the use of prophylactic NPWT cannot be supported. Larger randomized trials are needed in order to determine health outcomes and cost effectiveness (Gestring, 2018).

Discontinuation criteria for *incisional* NPWT have not been clearly defined and may vary according to incision and patient factors. Reported duration of incisional therapy varies between 1 and 5 days in the literature. Reddix et al. (2009) reported discontinuation of incisional NPWT at the point when no edema fluid was evident in the device canister for 12 hours, usually 24 to 72 hours after surgery.

There are a number of non-powered, portable, disposable NPWT systems. The Smart Negative Pressure (SNaP®) Wound Care System, received 510(k) clearance from the FDA in 2009 and is designed to remove small amounts of exudate from chronic, traumatic, dehisced, acute, or subacute wounds and diabetic and pressure ulcers. The device consists of a cartridge that acts as the negative pressure source, a dressing, and a strap and can be worn under clothing. The cartridge utilizes specialized springs that generate continuous negative pressure and is preset at negative 75, 100, or 125 mmHg, weighs less than 3 ounces, and has a 60 cc capacity. The dressing is a hydrocolloid dressing with an antimicrobial gauze wound interface layer. (Powered NPWT systems usually have a foam-based interface layer.)

A single use, disposable NPWT device, the PICO™ system, received 510(k) clearance from the FDA in 2012 and is designed to remove low to moderate amounts of exudate. The system uses batteries instead of electrical power and instead of using a canister, the exudate is absorbed into the dressing. The pump is programmed to stop working after 168 hours (7 days) of use and will not restart after that time, even with new batteries.

According to one manufacturer (Smith-Nephew), optimal wound healing has occurred when:

- Initial therapy objectives have been met
- 100% granulation tissue in the wound bed
- Granulation tissue level with the surrounding skin
- Patient's overall condition/wound is improving
- Wound bed is ready to take a skin graft/flap
- Exudate levels less than 20-50 mls per day

- No improvement/reduction in size of wound is seen in the wound bed following two consecutive dressing change

The use of the disposable, single use portable NPWT systems are not supported in scientific literature. Clinical trials fail to provide sufficient evidence to support improvement in net health outcomes compared to alternatives (Armstrong et al., 2012, Gabriel et al., 2013, and Hudson et.al. 2013)

PRESSURE ULCERS

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 includes 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.

LIST OF DEVICE NAMES U.S. FOOD AND DRUG ADMINISTRATION 510(K) CLEARANCE

- ActiV.A.C.® Therapy Unit
- Chariker-Jeter Wound Sealing Kit
- Engenex® Advanced NPWT System
- Exusdex® wound drainage pump
- EZCARE Negative Pressure Wound Therapy
- Chariker-Jeter Wound Sealing Kit
- InfoV.A.C. ® Therapy Unit
- Invia Liberty Wound Therapy
- Invia Vario 18 c/i Wound Therapy
- Medela® Invia Liberty pump
- Mini V.A.C.®
- NPD 1000 Negative Pressure Wound Therapy System
- Prodigy™ NPWT System (PMS-800 and PMS-800V)
- PRO-I™
- PRO-II™
- PRO-III™
- RENASYS™ EZ Negative Pressure Wound Therapy
- SVEDMAN™ and SVED™ Wound Treatment Systems
- V.A.C.® ATS™
- V.A.C.® Freedom™
- V.A.C.® Instill Device

- V.A.C.® Therapy Unit
- V.A.C.® (Vacuum Assisted Closure™)
- V1STA Negative Pressure Wound Therapy
- Venturi™ Negative Pressure Wound Therapy

Note: This list is not all inclusive.

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POLICY UPDATE HISTORY

08/24/2022	Approved in Medical Policy Committee
09/13/2022	Approved in QI/UM
10/10/2022	Approved in Governance