Negative Pressure Wound Therapy

Policy Number: 2015M0077A  Effective Date: May 1, 2015

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

Negative Pressure Wound Therapy (NPWT) is defined as the application of subatmospheric pressure to a wound to remove exudate and debris from wounds.

This policy describes negative pressure wound therapy (NPWT) as an adjunct treatment for slow healing or nonhealing acute or chronic wounds that have not responded to standard treatment. NPWT may be also used for acute fasciotomy wounds to intentionally delay healing to avoid compartment syndrome.

NPWT with instillation (NPWTi) is discussed as an aid in the treatment of wounds which are either at risk of infection or already infected or that have not responded to NPWT without instillation.

NPWT and NPWTi are prescribed by the attending surgeon or wound care physician. The application of NPWT bandages and set up of the NPWT or NPWTi device are performed by nurses or other healthcare specialists trained in wound care.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

A negative pressure wound therapy (NPWT) pump is considered MEDICALLY NECESSARY for any of the following:

1. Ulcers and Wounds in the Home Setting:
   - Stage III or IV pressure ulcer, neuropathic ulcer (e.g., diabetic ulcer), venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology

2. Ulcers and Wounds Encountered in an Inpatient Setting:
   - Complications of a surgically created wound (e.g., dehiscence, poststernotomy disunion with exposed sternal bone, poststernotomy mediastinitis, or postoperative disunion of the abdominal wall)
   - Traumatic wound (e.g., preoperative flap or graft, exposed bones, tendon or vessels) where there is need for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments)
   - Upper and lower extremity fasciotomy wounds in adults

NPWT may be considered MEDICALLY NECESSARY when treatment is ordered to continue beyond discharge to the home setting.

Negative-pressure wound therapy with instillation (NPWTi) is considered EXPERIMENTAL AND/OR INVESTIGATIONAL due to inadequate clinical evidence in published, peer-reviewed medical literature. Randomized, controlled studies are needed to demonstrate the benefit of NPWTi in wound therapy.
Clinical Considerations:
The use of NPWT is contraindicated in patients with the following conditions: active bleeding, anticoagulant use, difficult wound hemostasis, exposed vital organs, inadequately debrided wounds, untreated osteomyelitis, necrotic tissue with eschar, malignancy in the wound, or wounds having fistulas to organs or body cavities.

BACKGROUND:
Wound healing is a response to tissue injury that is a dynamic, interactive process taking place in three phases: inflammatory, proliferative, and tissue remodeling. The inflammatory response is immediate. In healthy individuals, the proliferative phase begins approximately 2 to 3 days after wounding. In the final phase of wound healing, organized restructuring of collagen takes place, and epithelial cells finally close the wound.

In healthy individuals with small wounds, the healing of wounds requires minor to no medical intervention. However, wound healing may be slow or incomplete if one of the healing stages is impaired, such as may occur with secondary infections or in the presence of other underlying conditions, such as diabetes or venous insufficiency. Acute and subacute wounds present a medical problem if they are large, especially if bones and tendons are exposed and, therefore, are not amenable to primary closure. Chronic wounds can occur secondary to a number of conditions, including venous insufficiency, pressure, trauma, diabetes or vascular disease. Treatment options for large acute, subacute or any size of chronic wounds often involve a complex wound care regimen, including aggressive debridement, antibiotic treatment and frequent changes of moisture-retentive dressings. A common treatment option for wounds that are not amenable to primary closure is the use of full-thickness or split-thickness skin grafts.

Negative pressure wound therapy (NPWT) is another option. It is performed for the purpose of providing a controlled, moist wound bed conducive to healing. This is achieved by placing custom-fit foam or gauze dressings over the wound, covering the dressings with a semi-permeable, self-adhesive drape, and applying subatmospheric (negative) pressure over the dressing-wound interface. The dressing and drape create a sealed wound environment which reduces the risk of infection from external sources, maintains a moist wound environment to help prevent desiccation of the superficial layer, and allows for suction on the wound bed which promotes tissue granulation and healing.

NPWT with instillation (NPWTi) involves irrigating, or instilling, the site of a wound with a topical solution, generally one consisting of saline or containing an antiseptic or antimicrobial substance. The instilled solution is then removed via the application of negative pressure. NPWTi is being studied as an aid in the treatment of wounds which are either at risk of infection or already infected or that have not responded to NPWT without instillation.

REGULATORY STATUS:
1. U.S. FOOD AND DRUG ADMINISTRATION (FDA): The V.A.C.® Therapy System (Kinetic Concepts Inc., or KCI), the first negative pressure wound therapy device to be approved by the FDA, initially received 510(k) approval for promoting wound healing on March 14, 1995. Labeling changes, approved on January 18, 2000, list the intended uses of V.A.C. when ordered by a physician for promoting wound healing in patients who would benefit from vacuum-assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or intermittent negative pressures. These include: chronic, acute, traumatic, subacute and dehisced wounds; diabetic ulcers; pressure ulcers; flaps; and grafts (CDRH, 2000). The V.A.C. received 510(k) clearance to include the indication of partial-thickness burns (CDRH, 2002) and venous insufficiency (CDRH, 2009a).
Subsequently, numerous wound suction devices have received 510(k) approval. The following manufacturers and devices are listed in alphabetical order. The list is not all-inclusive and does not include all models available from each of the manufacturers.

- Accuro Medical Products LLC • WoundPro Apex (CDRH, 2011a)
- ATMOS Inc.
  - ATMOS S041 Wound™ (CDRH, 2009a)
- Boehringer Wound Systems LLC
  - Engenex™ Advanced NPWT System (CDRH, 2006). This system is now licensed to ConvaTec Inc. (Boehringer Wound Systems, 2008)
- BlueSky Medical Group Inc./Smith & Nephew Inc.
  - Versatile 1 EZCare™ Wound Vacuum System (CDRH, 2007)
  - Versatile 1™ Wound Vacuum System (CDRH, 2009b)
  - RenaSys™ EZ PLUS Negative Pressure Wound Therapy (CDRH, 2010a)
- Genadyne Biotechnologies Inc.
  - Genadyne A4-XLR8 Wound Vacuum System (CDRH, 2009c)
- Innovative Therapies Inc.
  - Sved® Wound Treatment System (CDHR, 2009d)
- Kinetic Concepts Inc.
  - V.A.C.® Therapy System, including ActiV.A.C®, InfoV.A.C.®, V.AC. ATS®, V.AC. Freedom® Therapy Systems; V.AC. Instill® Therapy System (CDHR, 2009e)
  - Open Abdomen Negative Pressure Therapy System (CDRH, 2009f)
  - Prevena™ Incision Management System (CDRH, 2010b)
- Medela® Inc.
  - Medela® INVIA Wound Therapy (Medela, 2008a)
- NeoGen Technologies Inc.
  - NeoGen One, Closed Wound Drain System (CDRH, 2009g)
- Premco Medical Systems Inc.
  - Prodigy™ NPWT System (CDRH, 2009h)
- Smith & Nephew
  - PICO Single Use Negative Pressure Wound Therapy System (CDRH, 2011b)
- Spiracur Inc.
  - SNaP® Wound Care System (CDRH, 2011c)
- Talley Medical
  - Venturi™ NPWTv.11 Advanced Vacuum System (CDRH, 2009i)
- The Medical Company
2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

Medicare does not have a National Coverage Determination (NCD) for Negative Pressure Wound Therapy. NPWT devices are considered Durable Medical Equipment (DME) products and, therefore, in the absence of an NCD, coverage is left to the discretion of one of four contracted DME Medicare Administrative Contractors (MACs); the patient’s state of residence determines which DME MAC processes the claim.

Local Coverage Determination (LCD) for Negative Pressure Wound Therapy Pumps (L27025):

A Negative Pressure Wound Therapy pump (E2402) and supplies (A6550, A7000) are covered when criterion A is met:

A. Ulcers and Wounds in the Home Setting:
The beneficiary 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, must 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 beneficiary’s medical record of evaluation, care, and wound measurements by a licensed medical professional, and
   b. Application of dressings to maintain a moist wound environment, and
   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 beneficiary has been appropriately turned and positioned, and
   b. The beneficiary has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see LCD on support surfaces), and
   c. The beneficiary’s moisture and incontinence have been appropriately managed

3) For neuropathic (for example, diabetic) ulcers:
   a. The beneficiary 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

EXCLUSIONS FROM COVERAGE:
An NPWT pump and supplies will be denied at any time as not reasonable and 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;
- Osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure;
- Cancer present in the wound;
- The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

NPWT systems, pumps and their associated supplies, that have not been specifically designated as being qualified to use HCPCS codes E2402 via written instructions from the Pricing, Data Analysis and Coding (PDAC) Contractor, will be denied as not reasonable and necessary.

No National Coverage Determination (NCD) for negative pressure wound therapy with instillation was identified on the CMS website. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers. No Local Coverage Determination (LCD) for negative pressure wound therapy with instillation.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS): Specialized wound treatment technology may be medically necessary for eligible MHCP recipients with wounds that have not responded to standard wound treatment for at least a 30 – 60 day period. Negative Pressure Wound Therapy (NPWT) may be medically necessary for eligible MHCP recipients with wounds of less than 30 days duration if the patient is inpatient and preparing for discharge.

CLINICAL EVIDENCE:
Numerous randomized, controlled trials have investigated negative pressure wound therapy for the use of healing wounds related to a number of conditions including fasciotomy, mediastinitis, skin grafts and diabetic ulcers. Negative-pressure wound therapy with instillation has been studied to a lesser extent.

SUMMARY:
There is moderate evidence from randomized controlled trials that negative pressure wound therapy (NPWT) improves wound healing in carefully selected adult patients who have: (1) chronic wounds that are refractory to or have failed standard therapies, or (2) subacute or acute wounds when delayed healing or nonhealing is likely due to factors such as inadequate blood flow or diabetic complications. However, although the feasibility and relative safety of NPWT has been demonstrated, the heterogeneity in wound type makes it difficult to determine which specific types of wounds are likely to respond to
NPWT. The results for different types of wounds and among individual patients may vary (e.g., surgical wounds may not receive clinically significant benefits beyond standard dressings). The best evidence was available for chronic ulcers. For treating upper and lower extremity fasciotomy wounds in adults, NPWT may be relatively efficacious and safe. Most notably, NPWT may reduce the number of secondary foot amputations in patients with diabetic foot ulcers. NPWT was safe overall and did not cause more complications than standard dressing. There is low-quality evidence from retrospective controlled studies that NPWT may reduce treatment failure and reinfection rates and shorten hospital length of stay in adult patients with poststernotomy mediastinitis compared with other standard therapies such as closed irrigation. There is moderate evidence that when compared with standard wound care, NPWT improves graft survival and healing and may also reduce hospital length of stay in adult patients who have acute or chronic wounds requiring skin grafting.
APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>172.x*, 173.x*</td>
<td>Skin cancer</td>
</tr>
<tr>
<td>250.8x*, 707.1x*</td>
<td>Diabetic ulcer</td>
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<td>447.1</td>
<td>Arterial insufficiency ulcer</td>
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<td>454.0</td>
<td>Stasis ulcer</td>
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<tr>
<td>519.2</td>
<td>Mediastinitis</td>
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<tr>
<td>707.0</td>
<td>Pressure ulcer, stage III and stage IV</td>
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<tr>
<td>879.8</td>
<td>Open wounds (multiple) of unspecified site</td>
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<tr>
<td>885.x*-887.x*</td>
<td>Traumatic amputation, upper limb</td>
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<tr>
<td>924.xx*</td>
<td>Contusion, hematoma</td>
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<td>929.x*</td>
<td>Crushing injury</td>
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<td>946.x*</td>
<td>Burns</td>
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<td>990, E926.9</td>
<td>Radiation ulcer</td>
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<tr>
<td>998.3x*</td>
<td>Dehiscence of wound</td>
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<td>V45.89, 519.2</td>
<td>Poststernotomy mediastinitis</td>
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<tr>
<th>ICD-9 Codes</th>
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<td>Diseases of mediastinum, not elsewhere classified</td>
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<tr>
<td>S31</td>
<td>Open wound of abdomen, lower back and pelvis</td>
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<tr>
<td>S51</td>
<td>Open wound of forearm</td>
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<tr>
<td>S91</td>
<td>Open wound of ankle and foot</td>
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<td>S98</td>
<td>Traumatic amputation of ankle and foot</td>
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<tr>
<td>T20 – T25</td>
<td>Burns and corrosions of external body surface, specified by site</td>
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<tr>
<td>I83.0</td>
<td>Varicose veins of lower extremities with ulcer</td>
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<tr>
<th>ICD-10 Codes</th>
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### MEDICAL POLICY

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<tr>
<td>A6550</td>
<td>Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories</td>
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<td>A9272</td>
<td>Wound suction, disposable, includes dressing, all accessories and components, any type, each</td>
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<td>E2402</td>
<td>Negative pressure wound therapy electrical pump, stationary or portable</td>
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<td>G0456</td>
<td>Negative pressure wound therapy, (e.g. vacuum assisted drainage collection)</td>
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<tr>
<td>97605</td>
<td>Wound assessment, and instruction(s) for ongoing care, per session</td>
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### REFERENCES:


### POLICY HISTORY:

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<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
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### QUESTIONS AND ANSWERS:

| Q1: | A1: |