Clinical Review Criteria

Negative Pressure Wound Therapy Pumps (NPWT)

Group Health Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Group Health reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Group Health's sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the patient's Medical Coverage Agreement or call Group Health Customer Service to determine coverage for a specific medical service.

Criteria

For Medicare Members
See [LCD for Negative Pressure Wound Therapy Pumps (L11489)](https://www.grouphealth.org).

For Non-Medicare Members

Initial Coverage:
An NPWT pump and supplies are covered for wound edema, exudate management and stimulation of granulation for an initial 14 day course when the following main criteria are met:

1) **Must complete the Group Health initial coverage request form and fax it to the DME staff at 877-290-4632.**

2) Ulcers and Wounds in the Home Setting:
   a) The patient has a Stage III or IV pressure ulcer, neuropathic/diabetic ulcer, venous insufficiency or arterial ulcer, or a chronic ulcer of mixed etiology. These wounds should have exudate, size and depth to require this specialized therapy. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried for 30 days unless edema and/or exudate mandates NPWT.

   i) For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures prior to application of NPWT:

   - Documentation in the patient’s medical record of evaluation, care, and wound measurements by a licensed medical professional.
   - Consideration of the following risk factors is addressed in the documentation
     - Risk for bleeding and hemorrhage?
     - Active treatment with anticoagulants or platelet aggregation inhibitors
     - Presence of
       - Friable vessels and infected blood vessels
       - Vascular anastomosis
       - Infected wounds
       - Osteomyelitis
       - Exposed organs, vessels, nerves, tendons, and ligaments
       - Sharp edges in the wound (i.e. bone fragments)
       - Spinal cord injury (stimulation of sympathetic nervous system)
       - Enteric fistulas
     - Requirement for
       - MRI
       - Hyperbaric chamber
       - Defibrillation
       - Size and weight
       - Use of device near the vagus nerve
       - Use of circumferential dressing application
       - Mode of therapy – intermittent versus continuous negative pressure
     - Application of dressings to maintain a moist wound environment.
• Debridement of necrotic tissue if present.
• Evaluation of and provision for adequate nutritional status.

ii) For Stage III or IV pressure ulcers:
• The patient has been appropriately turned and positioned.
• The patient’s moisture and incontinence have been appropriately managed.

iii) For neuropathic/diabetic ulcers:
• The patient with diabetes has been on a comprehensive diabetic management program, and
• A foot ulcer has been appropriately off-loaded.

iv) For venous insufficiency ulcers:
• Compression bandages and/or garments have been consistently applied only after Ankle-Brachial Index has been done per guidelines, and
• Leg elevation with alternating ambulation has been encouraged.

3) Goal of therapy is clearly stated

4) Ulcers and Wounds Encountered in an Inpatient Setting:
   a) An ulcer or wound (described in section A above) is encountered in the inpatient setting and, after wound treatments described under sections A-a through A-d have been tried or considered and ruled out, NPWT may be initiated.
   
   b) The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments).
   In either of the above situations, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting.
   
   c) Skin-flaps or grafts approved as covered by the health plan in advance of the procedure.

5) Contraindications for use:
   a) the presence in the wound of necrotic tissue with eschar, if debridement has not been carried out;
   b) untreated osteomyelitis within the vicinity of the wound;
   c) possibility of malignant cells present in the wound;
   d) the presence of a fistula to an organ or body cavity within the vicinity of the wound.
   e) Exposed vascular in the wound
   f) Exposed nerves in the wound
   g) Exposed anastomotic site
   h) Exposed organs
   i) Recent lab values for albumin equal to or less than 2.5, hemoglobin less than 10, or hematocrit less than 30.
   j) Pediatric patients (newborns, infants and children)

Continued Coverage:
For wounds and ulcers described under sections A and B of Initial Coverage, once placed on an NPWT pump with supplies, in order for coverage to continue a licensed medical professional must do the following:

1) Must complete the Group Health continued coverage request form and fax it to the DME staff at 877-290-4632.

2) On a regular basis:
   a) directly assess the wound(s) being treated with the NPWT pump;
   b) supervise or directly perform the NPWT dressing changes.

3) On at least a weekly basis, document changes in the ulcer’s dimensions and characteristics and the degree of granulation and management of exudate.

4) Laboratory values at monthly intervals to show a contraindication does not exist
5) If these criteria are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not medically necessary.

**When Coverage Ends:**
For wounds and ulcers described under sections A and B of Initial Coverage, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:
1) Criteria for Continued Coverage cease to occur.
2) In the judgment of the treating physician, adequate wound granulation has occurred to the degree that NPWT may be discontinued.
3) Any measurable degree of wound healing has failed to occur over the prior 14 days. There must be documented in the patient’s medical records quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented, over a specified time interval. The recorded wound measurements must be consistently and regularly updated and must have demonstrated progressive wound healing from week to week.
4) NPWT should be ordered for a 2 week period of time as wounds are expected to change with this therapy. Once equipment or supplies are no longer being used for the patient, whether or not by the physician’s order, the provider should be directly contacted and the delivery of further supplies stopped. Pumps must be returned to the provider for billing purposes and cleaning.

**Supplies:**
1) Coverage is provided up to a maximum of 6 dressing kits (A6550) per wound per 14 day period unless there is documentation that the wound size requires more than one dressing kit for each dressing change. Dressings should be changed based on the patient’s condition and the condition of the wound but normally not more frequently than 3 times a week.
2) Coverage is provided up to a maximum of 2 canister sets (A7000) per 14 day period unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). For high volume exudative wounds, a stationary pump with the largest capacity canister must be used. Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) will be denied as not medically necessary.

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**Background**
Negative pressure wound therapy (NPWT) is a wound dressing system that was designed to promote wound healing through the use of subatmospheric pressure to the wound surface. NPWT systems include a vacuum pump, drainage tubing, and a dressing set. To place the device, the wound is covered or packed with a foam or gauze dressing and then secured using an adhesive film drape. A vacuum pump connected to the draining tube(s) in the wound dressing is used to apply pressure to the wound surface in the range of -50 to -125 mmHg. The precise mechanism through which NPWT aids the healing process is not fully understood; however, it has been suggested that NPWT may aid in the healing process through increasing local blood flow, increasing granulation tissue, reducing bacterial contamination, reducing wound area, reducing edema and exudate, and changes to the microenvironment (AHRQ 2009, Webster 2011).

Negative pressure therapy has been used in clinical applications for over 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 technique is also known as vacuum assisted closure (VAC), negative pressure wound therapy (NPWT), vacuum sealing technique (VST), sealed surface wound suction (SSS), subatmospheric pressure therapy or dressing, foam suction dressing, and vacuum pack technique (VPT). The technology generally involves putting a dressing
(foam or gauze) into the wound cavity, connecting it to a vacuum pump, and sealing the area with an adhesive film. The vacuum pump creates and maintains a subatmospheric pressure (intermittent or continuous) in the range of -50 to -125 mmHg. The default setting is -125 mmHg, and the pressure may be titrated up by 25 mmHg increments when there is excessive drainage or a large wound volume, or titrated down when the patient is elderly, nutritionally compromised, or has a risk of excessive bleeding. Dressings are usually changed every 48 hours, or every 12-24 hours if the wound is infected. The mechanism by which NPWT is believed to promote wound healing is unclear. In theory it may increase dermal perfusion, stimulate granulation tissue formation, reduce the edema and interstitial tissue fluid, reverse tissue expansion, and/or reduce bacterial colonization. It is also thought that the vacuum pressure may act as an effective skin graft splint over irregular surfaces. The therapy cannot be used as a replacement for surgical debridement, but as a complementary treatment. It is contraindicated for use in wounds with necrotic tissue, exposed vital structures, untreated osteomyelitis, unexplored fistulae and malignant wounds. Adverse effects include pain and damage to the skin around the wound (Braakenburg 2006, Bovill 2008, Wild 2008, Preston 2008).

Acute and chronic wounds and are a major cause of morbidity and impaired quality of life. They affect at least 1% of the population and represent a significant risk factor for hospitalization, amputation, sepsis, and even death. Wound healing is a complex series of events, broadly classified into inflammatory, proliferative, and remodeling phases. The healing process may be compromised by arterial or venous insufficiency which can prevent or delay healing and/or increase the risk of recurrent wound infections. The treatment of difficult-to-manage and chronic wounds remains a significant challenge to practitioners, a cause of pain and discomfort to the patients, and costly (Gregor 2008, Sadat 2008).

For centuries, gauze has been used in local wound care, mainly due to its low price and simplicity. In 1950s, a new concept, that wound healing is optimal when it is kept in a moist environment rather than air dried, was introduced. Since then, a large variety of occlusive or semi-occlusive dressings, topical applications, and other products were developed for the treatment of all kinds of wounds. Modern wound-healing agents include hydrocolloidal, alginates, hydrogels, hydrofiber, paraffin gauze dressings, as well as many others types of moist dressings and topical agents. The choice of the ideal regimen remains controversial due to the lack of good evidence from well conducted RCTs, and depends mainly on the clinicians’ preference (Chaby 2007, Gregor 2008, Ubbink 2009).

Skin grafts are used to promote healing in complex wounds with tissue loss. Successful skin grafting relies on the ability of the skin graft to integrate with the recipient wound bed. Bolstering the graft to the wound bed by applying a dressing along with positive pressure is used to improve integration with the wound bed and minimize seroma formation. NPWT is an alternative to standard bolstering techniques. It has been suggested that NPWT offers all of the advantage of standard bolstering in addition to other advantages such as active fluid removal and easier patient mobilization (Runkel 2011).

NPWT systems are FDA approved for use in patients with chronic, acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers, flaps, and grafts. The device is contraindicated for use in wounds with exposed vital structures, devitalized tissue, malignant tissue, untreated osteomyelitis, or in patients with untreated coagulopathy or allergy to any component required for the procedure (AHRQ 2009). NPWT was reviewed by MTAC in 1999, 2003, and 2008 for the management of chronic wounds and did not meet MTAC evaluation criteria. It is being re-reviewed for a new indication.

### Medical Technology Assessment Committee (MTAC)

<table>
<thead>
<tr>
<th>Date</th>
<th>Evidence Conclusion</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>02/10/99</td>
<td>The efficacy of the VST cannot be determined from the combination of these widely disparate studies/case series</td>
<td>The use of Vacuum Assisted Closure</td>
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<td>Date</td>
<td>Evidence Conclusion</td>
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<td>08/13/03</td>
<td>because of the widely heterogeneous samples, varying methods and application of the technique; small sample sizes, possible selection and observation bias, and the absence of comparison groups. In addition, there are a number of unresolved issues surrounding this technique, including but not limited to:&lt;br&gt;  ▪ which wounds are ideally suited for the application of this technique;&lt;br&gt;  ▪ the optimal conditions in which the technique can/should be applied;&lt;br&gt;  ▪ the ideal pressure required;&lt;br&gt;  ▪ ideal delivery of the negative pressure, e.g., by vacuum pump or bottle;&lt;br&gt;  ▪ when the wound dressing should be applied. Further studies, preferably blinded, randomized control trials are warranted to determine the efficacy of this technique/device.</td>
<td>for the treatment of wounds to promote healing does not meet the GHC Medical Technology Assessment Criteria 1. There is insufficient scientific evidence that this treatment is medically effective and therefore GHC criteria 2-5 are not met. In the absence of adequate, well-designed studies of effectiveness, the medical appropriateness of this technology (GHC Criteria 6) cannot be determined.</td>
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<td>04/06/09</td>
<td>The best evidence on VAC consists of two RCTs, each with fewer than 30 patients. Both are limited by their small sample sizes which makes selection bias likely and results in low statistical power. The two studies had different findings. Ford found no significant differences in wound healing between VAC and gel. Joseph found a statistically significant greater reduction in wound volume, width and depth with VAC compared to traditional saline wet-to-moist (WM) dressings. Joseph had the stronger methodology—more complete follow-up and consistency between the unit of randomization and the unit of analysis. Although the Joseph RCT suggests that VAC may be superior to traditional WM dressings, additional research is needed with larger sample sizes and consideration of potential selection bias/confounding.</td>
<td>The use of vacuum assisted closure in the treatment of non-healing wounds does not meet the Group Health Medical Technology Assessment Criteria.</td>
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<td>The largest published trial to date (Blume et al, 2008)</td>
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randomized 341 patients with diabetic foot ulcers to receive negative pressure wound therapy (NPWT) or advanced moist wound therapy (AMWT). All participants in the two groups also underwent wound debridement and off-loading. The results of the trial showed a significantly higher rate of complete ulcer closure in the patients receiving NPWT vs. AMWTs. The study was randomized and controlled, however, it had several limitations including unblinding of the patients and physicians which is a potential source of bias as it could influence the patient motivation and the care provided. Patients were treated at home or in a hospital setting and there is no indication whether they were given the same care and therapy e.g. equal pressure relief, intermittent or continuous negative atmospheric pressure, debridement, antibiotics, and other potentially confounding factors. Moreover, the study had a high drop-out rate and was financially supported by the manufacturer of the device.

Conclusion
- There is insufficient published evidence to date to determine whether topical negative pressure therapy is more effective than alternative wound dressings as regards rate of healing, pain management and quality of life.
- There is insufficient published evidence to date to determine that topical negative pressure therapy is safe to use in patients with acute or chronic wounds.

12/19/2011
A RCT that included 60 subjects with acute traumatic injuries and skin loss evaluated the effectiveness of NPWT compared to dressings without NPWT. Results from this study suggest that NPWT may lead to less graft loss, less frequent regrafting, and reduced time from patient intervention to discharge compared to with dressings without NPWT (Llanos 2006).

<table>
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<tr>
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<th>NPWT</th>
<th>Control</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Loss of grafted area (cm²)</td>
<td>0.0 (0-12)</td>
<td>4.5 (0-53)</td>
<td>0.001</td>
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<tr>
<td>Percentage of graft loss</td>
<td>0.0 (0-62)</td>
<td>12.8 (0-76)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Days from grafting to discharge</td>
<td>8 (7-13)</td>
<td>12 (7-23)</td>
<td>0.001</td>
</tr>
<tr>
<td>Need for 2nd coverage procedure</td>
<td>5 (16.7)</td>
<td>12 (40.0)</td>
<td>0.045</td>
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Conclusion:
There is some evidence to support the use of NPWT as a splint or bolster for skin grafts.
Evidence/ Source Documents

<table>
<thead>
<tr>
<th>Date of Literature Search</th>
<th>Articles</th>
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<tr>
<td>2/10/1999</td>
<td>Articles were selected based on study type. There was one prospective clinical trial (Mullner et al., 1997), no meta-analyses or cohort studies, and a few case series. An evidence table for the clinical trial. No evidence tables were created for the case series, as the sample sizes were either too small, or the not described in sufficient detail. Case series were reviewed by abstract, and a brief summary of their findings is included.</td>
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Reference
Mullner T, Mrkonjic L, Kwasny O, Vecsei V. The use of negative pressure to promote the healing of tissue defects: a clinical trial using the vacuum sealing technique. British Journal of Plastic Surgery 1997 Apr;50(3):194-9. See Evidence Table

| 8/13/2003                  | The search yielded 144 articles. Many of these were review articles, opinion pieces, dealt with technical aspects of wound closure techniques or were on related procedures. There were two small randomized controlled trials using the VAC system. No non-randomized comparative studies were identified. The two RCTs were critically appraised. |

| 4/9/2009                  | The search yielded over 300 articles on negative pressure wound therapy. Many were review articles, opinion pieces, dealt with technical aspects of wound closure techniques, or were unrelated to the current review. There were four systematic reviews with or without meta-analyses, four RCTs, and a number of case series published after the last MTAC review of the technology. |
| Gregor et al’s 2008 review included both randomized and non-randomized trials but pooled the results of each group of studies for only one surrogate outcome. In two Cochrane reviews (Ubbink 2008, Wasiak 2007), the authors could not pool the results in meta-analyses due to the small number of studies, poor reporting, heterogeneity in endpoints and comparator treatments. Another published meta-analysis (Sadat et al, 2008) included two small negative trials (total of 70 participants) on the use of VAC for various types of ulcers, and one positive larger trial (N= 162) on its use after diabetic foot amputation, which skewed the results of the meta-analysis. Only one RCT (Blume 2008) had clinically important outcomes, relatively large sample size, and generally valid methodology. Both the review with a meta-analysis as well as the RCT with generally valid methodology were selected for critical appraisal: |

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NPWT for skin grafts or skin substitutes was reviewed in 2010 by NHS Quality Improvement Scotland (NHS QIS). This review found some evidence to support the use of NPWT for wounds caused by burns or trauma that require a skin graft as treatment and certain types of venous leg ulcers with split-thickness pinch skin graft. The recommendations from NHS QIS were based on evidence from two high-quality and two low-quality randomized controlled trials (RCTs) as well as several observational studies (NHS QIS 2010). Since the NHS QIS review, the literature search revealed two additional RCTs that evaluated the safety and efficacy of NPWT for skin grafts or skin substitutes. These studies were not selected for review due to methodological limitations (i.e., small sample size, high loss to follow-up, etc.) (Chio 2010, Petkar 2011). One of the high quality trials evaluating the use of NPWT was not used for bolstering and therefore was not selected for review (Vuerstaek 2006). The other high quality trial included in the NIH QIS was selected for review.

The following study was selected for critical appraisal: