KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Negative Pressure Wound Therapy

- Pumps
- PICO (non-powered)
- SNAP (non-powered)
- Single Use Negative Pressure Wound Therapy (s-NPWT) for the Prevention of Surgical Site Infections (SSIs) in Closed Surgical Incisions

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Negative Pressure Wound Therapy Pumps (L33821) for traditional NPWT covered under DME Wound Care (L37228) *Mentions disposable NPWT (dNPWT)*
Local Coverage Article	Negative Pressure Wound Therapy Pumps (A52511) for traditional NPWT covered under DME
MLN Matters Article	Clarification of Billing and Payment Policies for Negative Pressure Wound Therapy Using a Disposable Device *For disposable NPWT provided by Home Health Agency*

For Non-Medicare Members

Service	Criteria
Initial Coverage—Traditional Negative Pressure Wound Therapy Pump (tNPWT)	Traditional Negative Pressure Wound Therapy Pumps (tNPWT) A traditional NPWT (tNPWT) pump and supplies are covered for wound edema, exudate management and stimulation of granulation for an initial 30-day course when the following main criteria are met: A. Ulcers and Wounds in the Home Setting: 1. 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: (a) Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional.

Back to Top

(b) Consideration of the following risk factors is addressed in the documentation
(i) Risk for bleeding and hemorrhage
(ii) Active treatment with anticoagulants or platelet aggregation inhibitors
(iii) 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

(c) 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

(d) Application of dressings to maintain a moist wound environment.
(e) Debridement of necrotic tissue if present.
(f) Evaluation of and provision for adequate nutritional status.

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

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

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

B. Goal of therapy is clearly stated

C. Ulcers and Wounds Encountered in an Inpatient Setting:
1. 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.
2. 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.

Back to Top

	3. Skin-flaps or grafts approved as covered by the health plan in advance of the procedure. D. Contraindications for use: 1. The presence in the wound of necrotic tissue with eschar, if debridement has not been carried out 2. Untreated osteomyelitis within the vicinity of the wound 3. Possibility of malignant cells present in the wound 4. The presence of a fistula to an organ or body cavity within the vicinity of the wound 5. Exposed vascular in the wound 6. Exposed nerves in the wound 7. Exposed anastomotic site 8. Exposed organs 9. Recent lab value for albumin equal to or less than 2.5. 10. Pediatric patients (newborns, infants and children)
Initial Coverage—Disposable, single-use Negative Pressure Wound Therapy (i.e., SNAP, Prevena, V.A.C. VIA)	Disposable, single-use Negative Pressure Wound Therapy for **chronic wound and ulcers** A. The SNAP™ Therapy System (Acelity/KCI) may be used instead of traditional NPWT if **ALL** of the following criteria are met: B. Must complete the Kaiser Permanente initial coverage request form and fax it to the DME staff at 877-290-4632. C. These wounds should have exudate, size and depth to require this specialized therapy. A complete wound therapy program described by criterion 1.B.1.i and criteria 1.B.1.ii, 1.B.1.iii, or 1.B.1.iv, as applicable depending on the type of wound, should have been tried for 30 days. 1. Wound size < 13 cm x 13 cm 2. Wound drainage ≤ 180 mL/week (20mL/day) 3. Change dressing 2x/week at minimum; dispose of cartridge when full (typical cartridge holds 60 mL) D. Contraindications for use of disposable NPWT (SNAP) 1. Inadequately drained wounds 2. Necrotic tissue such as eschar or adherent slough 3. Exposed blood vessels, anastomotic sites, organs, tendons, or nerves 4. Wounds containing malignancy 5. Fistulas 6. Untreated osteomyelitis 7. Actively bleeding wounds Single Use Negative Pressure Wound Therapy (s-NPWT) may have a role in the prevention of surgical site infections for high-risk surgeries. However, in this setting Single Use Negative Pressure Wound Therapy (s-NPWT) is considered a surgical dressing and covered by the procedure billing code and is not separately reimbursable under the Prepayment Bill Review – Line item Deduction payment policy.
Continued Coverage (tNPWT/SNAP)	For wounds and ulcers described under sections 1 and 2 of Initial Coverage, once placed on any type of NPWT pump with supplies, for coverage to continue a licensed medical professional must do the following: 1) 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 2) On at least a weekly basis, document changes in the ulcer's dimensions and characteristics and the degree of granulation and management of exudate A. If using SNAP: If wound increases in size or is producing amounts of exudate above the parameters for SNAP, may need to evaluate the need for tNPWT or other wound management strategies.

Back to Top

	3) Laboratory values at monthly intervals to show a contraindication does not exist 4) 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 tNPWT/SNAP	1) 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: A. Criteria for Continued Coverage cease to occur. B. In the judgment of the treating physician, adequate wound granulation has occurred to the degree that NPWT may be discontinued. C. Wound is not healing progressively 1. Progressive wound healing has failed to occur over the prior 30 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. 2. If using SNAP: If progressive wound healing has failed to occur, or wound increases in size or is producing amounts of exudate above the parameters for SNAP. D. NPWT should be ordered for a 30 day 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 provided should be directly contacted and the delivery of further supplies stopped. Traditional NWPT Pumps must be returned to the provider for billing purposes and cleaning.
Supplies	**Supplies for tNPWT:** 1) Coverage for tNPWT is provided up to a maximum of 6 dressing kits (A6550) per wound per 30-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 for tNPWT is provided up to a maximum of 2 canister sets (A7000) per 30-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. **Supplies for SNAP replacement:** 1) Coverage for SNAP is provided up to a maximum of 4 devices per 30-day period unless there is documented evidence of a larger volume of drainage requiring more frequent replacement. 2) The two codes of 97607 and 97608 should only be used when the provider is either initially applying an entirely new SNAP device or removing a SNAP device and replacing it with an entirely new one as clinically required. These codes may not be used if only a dressing change is performed for a SNAP system.
PICO	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Back to Top

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KAISER PERMANENTE will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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 other 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

 Back to Top

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.

Evidence Source Documents
Vacuum Assisted Closure for the Treatment of Wounds
Vacuum Assisted Closure in the Treatment of Non-Healing Wounds
Negative Pressure Wound Therapy in the Treatment of Skin Grafts and Flaps
SNAP & PICO Device

Medical Technology Assessment Committee (MTAC)

Vacuum Assisted Closure for the Treatment of Wounds

02/10/1999: MTAC REVIEW

Evidence Conclusion: The efficacy of the VST cannot be determined from the combination of these widely disparate studies/case series 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:

- which wounds are ideally suited for the application of this technique;
- the optimal conditions in which the technique can/should be applied;
- the ideal pressure required;
- ideal delivery of the negative pressure, e.g., by vacuum pump or bottle;
- when the wound dressing should be applied.

Further studies, preferably blinded, randomized control trials are warranted to determine the efficacy of this technique/device.

Articles: 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. 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.

The use of Vacuum Assisted Closure for the treatment of wounds to promote healing does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Vacuum Assisted Closure in the Treatment of Non-Healing Wounds

08/13/2003: MTAC REVIEW

Evidence Conclusion: 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.

Articles: 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. Ford CN, Reinhard ER, Yeh D. et al. Interim analysis of a prospective, randomized trial of Vacuum-Assisted Closure versus the Healthpoint System in the management of pressure ulcers. *Ann Plast Surg*

 Back to Top

2002; 49: 55-61. See Evidence Table. Joseph E, Hamori CA, Bergman S. A prospective, randomized trial of vacuum-assisted closure versus standard therapy of chronic non-healing wounds. *Wounds* 2000; 12: 60-67. See Evidence Table.

The use of vacuum assisted closure in the treatment of non-healing wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/06/2009: MTAC REVIEW

Vacuum Assisted Closure in the treatment of Non-Healing Wounds

Evidence Conclusion: There is a lack of high quality randomized controlled trials on the use of negative pressure therapy for wound healing. The best published clinical evidence consists of few RCTs with flawed methodology. The majority of the studies were small, had inadequate power to detect differences between treatment groups, were unblinded, and had little or no information on the baseline characteristics of the participants, or causes of dropouts. The trials mainly used surrogate outcomes as reduction in wound size and formation of granulation tissue, rather than complete healing of the ulcer. The largest published trial to date (Blume et al, 2008) 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.
Conclusions: 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.
Articles: 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: Gregor S, Maegele M, Sauerland S, et al. Negative pressure wound therapy. A vacuum of evidence? Arch Surg 2008; 143:189-196. See Evidence Table.
Blume PA, Ayala J, Walters J, et al. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers. A multicenter randomized controlled trial. Diabetes Care 2008;31: 631-636. See Evidence Table.

The use of vacuum assisted closure in the treatment of non-healing wounds does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Negative Pressure Wound Therapy in the Treatment of Skin Grafts and Flaps

12/19/2011: MTAC REVIEW

Evidence Conclusion: An 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).

	NPWT	Control	P-value
	Median (range)		
Loss of grafted area (cm^2)	0.0 (0-12)	4.5 (0-53)	0.001

Back to Top

Percentage of graft loss	0.0 (0-62)	12.8 (0-76)	<0.001
Days from grafting to discharge	8 (7-13)	12 (7-23)	0.001
	Number (%)		
Need for 2nd coverage procedure	5 (16.7)	12 (40.0)	0.045

Conclusion: There is some evidence to support the use of NPWT as a splint or bolster for skin grafts.
Articles: 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:
Llanos S, Danilla S, Barraza C, et al. Effectiveness of negative pressure closure in the integration of split thickness skin grafts. *Ann Surg.* 2006; 244:700-705. See Evidence Table.

The use of negative pressure wound therapy in the treatment of skin grafts and flaps does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

SNAP & PICO Device

02/09/2015: MTAC REVIEW

Evidence Conclusion: First and foremost, it should be established that there is a lack of evidence to support the general use of NPWT. Previous MTAC critical appraisals have cited a lack of high-quality RCTs evaluating the use of NPWT for wound healing. To date, the best published clinical evidence consists of a few RCTs with flawed methodology due to limitations such as small sample size and inadequate power. Generally speaking, NPWT has been applied to a wide variety of wounds in varying locations, complexity and underlying pathology limiting the ability to make comparisons across studies. This limitation is demonstrated in a various systematic reviews with attempted meta-analyses that have failed to reach any definitive conclusions due to variable endpoints (Mendonca, Papini et al. 2006; Pham, Middleton et al. 2006; Sjögren, Malmsjö et al. 2006; Kanakaris, Thanasas et al. 2007; Wasiak and Cleland 2007; Bovill, Banwell et al. 2008; Group 2008; Noble-Bell and Forbes 2008; Ubbink, Westerbos et al. 2008; Ubbink, Westerbos et al. 2008; Dumville, Hinchliffe et al. 2013). *Effectiveness*: In 2011 and 2012, Armstrong and colleagues published an interim and final analysis with the overall aim of comparing NPWT with an ultraportable mechanically powered device with a traditional electrically powered device. Overall, the study enrolled 132 patients with lower-extremity diabetic and venous wounds. The primary outcome measurement was wound size reduction, however, data assessing the time for dressing change and user experience was also collected. The primary end point results indicated that the SNaP treated subjects were non-inferior to the VAC-treated patients at all follow-up points 4, 8, 12 and 16 weeks (p-value of 0.0054, 0.0047, <0.0001, and <0.0001, respectively). Exit surveys addressing quality of life (QoL) and activity were completed by 105 patients (79.5%) with the SNaP group consistently reporting less impact on activities such as sleep, mobility and socializing. Patient reporting of pain and discomfort associated with treatment, however, was similar in both groups with no statistical difference (Armstrong, Marston et al. 2011; Armstrong, Marston et al. 2012). [Evidence Table 1] *Safety:* In terms of safety, device related adverse events (AE) were similar in both groups with maceration being the most commonly reported complication. The investigators ultimately concluded that the treatment of wounds with a mechanically powered NPWT device resulted in similar wound healing outcomes as treatment with a traditional, electrically powered, NPWT device with less impact on the patient's quality of life. The evidence is limited by a variety of factors most notably, the use of an inadequate comparator. While NPWT is widely used, the current body of evidence is limited in supporting its effectiveness in promoting wound healing. Beyond that, limitations of the study's methodology include small sample size, as well as significant differences between groups in terms of wound size and age prior to treatment. Finally, it should be noted that the study was sponsored by Spiracur, Inc. the manufacturers of the SNaP® device. In addition, two of the investigators, Armstrong and Marston, have received research funding from both Spiracur and K.C.I. Conclusions: There is insufficient evidence to support the safety of the non-powered NPWT devices for treatment of patients with wounds. There is insufficient evidence to support the effectiveness of the non-powered NPWT devices for treatment of patients with wounds.

Back to Top

Articles: The literature search revealed a variety of articles relating to the general use of NPWT. Only a few articles were directly related to the use of non-powered or non-electrically powered NPWT devices including a small pilot trial (n=30) of the effect of the PICO device on surgical wound healing in patients with Crohn's disease (Pellino, Sciaudone et al. 2014), a small case series (n=20) describing experience with the PICO device (Hudson, Adams et al. 2013), and a small retrospective case-control study (n=78) comparing the SNaP™ device to a variety of other wound therapies (Lerman, Oldenbrook et al. 2010). There were no randomized control trials (RCTs) identified that compared non-powered/electrical NPWT to conventional wound care. Two publications were revealed that presented the interim and final results of a small RCT comparing the SNaP device with a standard powered VAC (Armstrong, Marston et al. 2011; Armstrong, Marston et al. 2012). The following articles were selected for critical appraisal: Armstrong DG, Marston WA, Reyzelman AM et al. Comparison of negative pressure wound therapy with an ultraportable mechanically powered device vs. traditional electrically powered device for the treatment of chronic lower extremity ulcers: A multicenter randomized-controlled trial. Wound Rep Reg. 2011; 19(2):173-180. Evidence Table 1.Armstrong DG, Marston WA, Reyzelman AM et al. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial. 2012;20(3):332-341. Evidence Table 1

The use of SNAP & PICO device in the treatment of negative wound pressure therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/14/2019: MTAC REVIEW
Evidence Conclusion:

- There is low-moderate quality evidence from a single open-label RCT suggesting that s-NPWT is superior to the traditional NPWT in treating venous leg ulcers (VLUs), or diabetic foot ulcers (DFUs) as regards reducing the wound area, and the ulcer depth and volume as well as time to complete closure in highly selected patients with chronic lower extremity ulcers.

- Low quality evidence from a sub-analysis of one open-label RCT suggests that SNaP may be superior to the traditional NPWT as regards wound size reduction and 50% wound closure when used in a highly selected group pf patients with venous leg ulcers.

- There is insufficient evidence to determine the safety of the single use NPWT in patients with lower extremity chronic wounds.

Articles: The literature search for studies on single use NPWT published after the last MTAC review of the technology, revealed one RCT that directly compared the efficacy of PICO versus traditional NPWT in the treatment of chronic ulcers in the lower extremities, and another RCT that compared a single use mechanically powered SNaP Wound Care System versus a traditional NPWT system for the management of venous leg ulcers. The rest of the published studies that evaluated the single use NPWT were either observational studies or RCTs that compared the devices versus conventional wound dressing (such as sterile gauze dressing, absorbent dressings, and silver-impregnated occlusive dressings). The results of these studies were pooled in five meta-analyses (MAs) identified by the search; three of which (Semsarzadeh et al, 2015, Watts et al, 2015, and De Vries et al, 2016) compared the outcomes of NPWT (t-NPWT and s-NPWT combined) versus conventional wound care. One MA (Strugala and Martin 2017); evaluated the effect of s-NPWT versus traditional dressing on the prevention of surgical site complications. and another (Singh et al, 2018) compared the effect of closed incision NPT (using PRAVENA system) also versus traditional dressing on reducing surgical site infections.

The following two RCTs that compared the single use NPWT versus the traditional NPWT were selected for critical appraised. None of the identified meta-analyses or the trials comparing the single use NPWT versus conventional/standard wound care was included as the aim of the current review is to compare the single use NPWT versus the traditional NPWT. See Evidence Table.

The use of SNAP & PICO device in the treatment of negative wound pressure therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

tNPWT - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

 Back to Top

HCPC Codes	Description
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
A7000	Canister, disposable, used with suction pump, each
E2402	Negative pressure wound therapy electrical pump, stationary or portable
K0743	Suction pump, home model, portable, for use on wounds
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq. in or less
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
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq. in

Disposable NPWT (including, but not limited to: SNAP, Prevena, V.A.C. VIA) - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
***not covered by Medicare**

CPT/HCPC Codes	Description
97607	Negative pressure wound therapy, (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608	Negative pressure wound therapy, (e.g., 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
A9272*	Wound suction, disposable, includes dressing, all accessories and components, any type, each

PICO - Considered Not Medically Necessary:
***not covered by Medicare**

CPT/HCPC Codes	Description
97607	Negative pressure wound therapy, (e.g., 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
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A9272*	Wound suction, disposable, includes dressing, all accessories and components, any type, each

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
12/12/2000	06/01/2010 MDCRPC, 04/05/2011 MDCRPC, 01/03/2012 MDCRPC, 12/04/2012 MDCRPC, 10/01/2013MPC, 08/05/2014MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC, 10/05/2021MPC, 10/04/2022MPC , 10/03/2023MPC2	07/11/2023

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Back to Top

Revision History	Description
10/26/2015	Changed codes for PICO and SNAP
06/02/2015	Codes Added
09/18/2017	Removed the requirement for Hemoglobin and Hematocrit
09/27/2017	Added LCA and MLN Matters Article
03/03/2020	MPC approved to adopt coverage policy for SNAP; Added October 2019 MTAC Review
04/07/2020	MPC approved to adopt new coverage criteria for SNAP
03/01/2022	MPC approved to adopt coverage criteria for dNPWT for SSI Prevention. 60-day notice required; effective 08/01/2022.
07/11/2023	MPC has approved to remove criteria for Single Use Negative Pressure Wound Therapy (s-NPWT) when applied in the operating room or apart from an encounter for the purpose of wound care. Requires 60-day notice effective 12/01/2023
07/24/2023	Updated initial duration for course of treatment to 30 days.

Back to Top