WARMING THERAPY AND ULTRASOUND THERAPY FOR WOUNDS

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COVERAGE RATIONALE
Warming therapy or noncontact normothermic wound therapy is unproven for the treatment of wounds.

The safety and efficacy of warming therapy or noncontact normothermic wound therapy for the treatment of chronic wounds has not been established in the published medical literature. Limitations of the existing studies include small samples, a lack of controls and/or randomization, short follow-up times, differences in standard therapy received by the treatment and control groups, and a paucity of statistical analyses of the results. These limitations create difficulties in drawing definitive conclusions about the relative efficacy and/or safety of this therapy for healing chronic wounds. Well-designed trials evaluating the efficacy and safety of warming therapy are needed to demonstrate that warming therapy is beneficial for health outcomes in patients with chronic wounds.

Low frequency ultrasound is unproven for the treatment of wounds.

Warming Therapy and Ultrasound Therapy for Wounds: Medical Policy (Effective 01/01/2014)

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Evidence for the use of low frequency ultrasound to treat wounds is limited and consists of studies that lack adequate sample sizes and proper control groups. Additional research with larger trials is needed to demonstrate that low frequency ultrasound is beneficial for health outcomes in patients with wounds.

**BACKGROUND**

Warming therapy or noncontact normothermic wound therapy uses a noncontact wound cover and a warming unit to apply radiant heat and maintain 100% relative humidity in a wound. The intent is to raise the wound temperature to increase blood flow and oxygen to the wound. The Warm-Up® Active Wound Therapy System is a device used for warming therapy, but according to Arizant Inc., this device is no longer marketed in the United States. Other warming therapy devices have been approved by the U.S. Food and Drug Administration (FDA).

Low frequency or low energy ultrasound using the Mist Therapy™ System has been developed to provide simultaneous cleansing and debridement of wounds. Treatment with this device involves holding an ultrasonic handset 1 cm away from the wound and applying a saline solution to the handset, generating a saline mist that is designed to carry low levels of ultrasonic energy into the wound. According to the device manufacturer, this treatment promotes healing of acute, traumatic, and chronic wounds by stimulating cellular activities that contribute to healing and by cleaning the wound surface. See the following Web site for more information: [http://www.celleration.com/](http://www.celleration.com/). Accessed September 22, 2013.

**CLINICAL EVIDENCE**

**Warming Therapy**

No studies that provide substantial new evidence regarding warming therapy for wounds were identified in a September 2013 literature search.

Results of the studies of noncontact normothermic wound therapy (NNWT) for treatment of stage III and IV pressure ulcers and neuropathic ulcers suggest that NNWT, either alone, or in conjunction with standard care and/or offloading, can increase healing rates and the incidence of complete healing (Whitney et al., 2001; Kloth et al., 2002; McCulloch and Knight, 2002; Alvarez et al., 2003). In some cases, these increases were nonsignificant trends, which may reflect the relatively modest treatment effect combined with the small sample sizes. These studies should be interpreted with caution since all of the studies were supported by the manufacturer of the NNWT system, which introduces the possibility of investigator bias. Small study populations, ranging from 17 to 56 wounds per study, lack of blinding, lack of or insufficient statistical analysis and substantial dropout rates further compromised the quality of the evidence. Patient selection criteria were not defined in some studies. Furthermore, long-term follow-up data assessing wound stability and recurrence rates are not available.

In a very small, randomized study evaluating the efficacy of NNWT combined with offloading for treatment of chronic skin wounds associated with osteomyelitis, mean healing time was increased in patients who received NNWT compared with those who received standard care and offloading. However, this difference did not reach statistical significance, and median wound healing times did not differ between groups (Karr, 2003).

Ellis et al. (2003) evaluated 33 patients with full-thickness pressure sores who were randomized to receive standard care or radiant heat therapy with a Warm-Up device. The Warm-Up device eradicated bacteria in 6 patients within 2 weeks of starting treatment compared to none in the standard care group. The significance of this study is limited by small sample size.

Forty-one patients with pressure ulcers were randomized to receive radiant heat dressing or hydrocolloid dressing. Fifty-seven percent of the patients using the radiant heat dressing device had complete ulcer healing compared to 44% of the control group. However, the difference was
Low Frequency Ultrasound

A randomized, controlled clinical study was conducted by Olyais et al. (2013) to compare the effectiveness of standard treatment and standard treatment plus either high frequency or noncontact low frequency ultrasound when treating chronic wounds, including venous leg ulcers. It was noted that a total of 90 people participated in the study, including 47 men and 43 women. It was also noted that the average age for the participants was 38.3 years old. Out of the 90 participants it was noted that 30 participants received standard care. Standard care was defined as follows: multilayered compression bandaging (40 mm Hg of pressure at the ankle graduated to 17 mm Hg to 20 mm Hg below the knee), nonadherent dressing, and regular debridement. Standard care dressing changes and ultrasound therapy were provided three times per week for 3 months or until healed. It was noted that 30 participants received standard treatment plus high-frequency ultrasound, which was delivered at 1-3 MHz for 5 to 10 minutes. The remaining 30 participants received standard treatment plus low-frequency ultrasound, which was delivered at 40 kHz for 4-10 minutes. The final results of this study were reported to show that the outcome of both methods of the ultrasound therapy were better than standard care alone. The result of this one study does not provide sufficient clinical data, to change the current unproven status of the use of low frequency ultrasound for the treatment of wounds. Additional studies and randomized trials are required to support and confirm the long and short term findings of this lone study.

Yoa et al. (2012) conducted a randomized clinical study designed to determine the effects of non-contact low frequency ultrasound (NCLF-US) devices when used for the treatment of chronic non-healing wounds. Subjects were randomly assigned to one of three groups: application of NCLF-US thrice per week (Group 1), NCLF-US once per week (Group 2) and the control (Group 3) that received no NCLF-US. All subjects received standard wound care plus offloading for a total of 4 weeks. Percent area reduction (PAR) of each wound compared to baseline was evaluated weekly. Twelve DFU patients, 2 (16·7%) type 1 and 10 (83·3%) type 2 diabetics, with an average age of 58 ± 10 years and a total of 12 foot ulcers were enrolled. Group 1 showed significant wound area reduction at weeks 3, 4 and 5 compared to baseline, with the greatest PAR, 86% (P < 0·05); Groups 2 and 3 showed 25% PAR and 39% PAR, respectively, but there were no statistically significant differences between Group 2 and Group 3 over time. Based on the information provided by this small randomized study the therapeutic application of NFLU three times per week allows for the best wound area reduction. The results of this study must be confirmed in a larger trial.

Ennis et al. (2005) conducted a multicenter, double-blinded randomized controlled trial to evaluate the Mist Therapy System for treatment of chronic diabetic foot ulcers. As an adjunct to standard wound care with saline moistened gauze dressings and debridement as needed, patients underwent true or sham Mist treatment in 3 sessions per week for 12 weeks. Although 133 patients were enrolled and considered in the intent-to-treat analysis, 78 patients (59%) were subsequently excluded leaving 27 patients in the treatment group and 28 in the sham group, which comprised the per protocol population. In the per protocol population, at week 11, the treatment group had a 56% decrease in wound exudation compared with the sham group. In the per protocol population, complete closure was achieved in 41% of patients in the treatment group versus 14% in the sham group at 12 weeks. The mean time to healing was 9.1 ± 0.6 weeks for the treatment group versus 11.7 ± 0.2 weeks for the sham group. Despite the improvements in wound exudation and wound closure for the treatment group versus the sham group, Mist Therapy was not associated with any statistically significant improvements in granulation tissue. According to the intent-to-treat analysis, the Mist Therapy System wound healing did not provide any statistically significant improvements in wound healing.

For patients who had wounds due to insufficient lower limb blood flow, another RCT found that Mist Therapy was associated with a statistically significant improvement in partial wound healing. After 12 weeks of treatment, greater than 50% wound healing occurred in 63% of patients who

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underwent Mist Therapy versus 29% of patients who underwent standard wound care alone (Kavros et al., 2007). The small study population limits the validity of this study. Furthermore, this study used 50% rather than 100% wound healing as the measure of success and did not report whether any patients achieved complete wound healing.

Watson et al. (2011) assessed the clinical effectiveness of weekly delivery of low dose, high frequency therapeutic ultrasound in conjunction with standard care for hard to heal venous leg ulcers in a multicentre, two arm randomized controlled trial. The study included 337 patients with at least one venous leg ulcer of >6 months’ duration or >5 cm(2) area and an ankle brachial pressure index of ≥ 0.8. The study evaluated weekly administration of low dose, high frequency ultrasound therapy for up to 12 weeks plus standard care compared with standard care alone. The two groups showed no significant difference in the time to healing of the reference leg ulcer. After adjustment for baseline ulcer area, baseline ulcer duration, use of compression bandaging, and study center, there was still no evidence of a difference in time to healing. There was no difference in time to complete healing of all ulcers, with median time to healing of 328 days with standard care and 365 days with ultrasound. There was no evidence of a difference in rates of recurrence of healed ulcers (17/31 with ultrasound vs 14/31 with standard care). There was also no difference between the two groups in health related quality of life; both for the physical component score and the mental component score, but there were significantly more adverse events in the ultrasound group. The authors concluded that low dose, high frequency ultrasound administered weekly for 12 weeks during dressing changes in addition to standard care did not increase ulcer healing rates, affect quality of life, or reduce ulcer recurrence.

In a randomized controlled trial, Taradaj et al. (2008) estimated the usefulness of therapeutic ultrasound for healing of venous leg ulcers in 81 patients. Patients in groups 1 and 2 were treated surgically. Patients in groups 3 and 4 were treated conservatively. Patients in groups 1 and 3 were additionally treated with the ultrasound (1 MHz, 0.5 W/cm(2)) once daily, six times a week for seven weeks. Comparison of the number of complete healed wounds indicated statistically significant differences between groups 1 and 4, 2 and 4, 3 and 4 in favor of groups 1, 2 and 3. Comparison of the other parameters also demonstrated more efficient therapy effects in groups 1, 2 and 3 than in group 4. There were no statistical differences in all examined parameters between groups 1, 2 and 3. The investigators concluded that ultrasound is an efficient and useful method only in conservatively treated venous leg ulcers. They state also that there are no special reasons for application of the ultrasound in surgically treated patients. They comment further that a well-conducted surgical operation is much more effective for a healing process than conservative pharmacological procedures. The small study population limits the validity of this study.

Driver et al. (2011) performed a meta-analysis and summarized the effects of noncontact low-frequency ultrasound (NLFU) therapy on healing of chronic wounds. The meta-analysis included 8 published studies that reported effects of NLFU on wound size and healing rate of chronic wounds in 444 patients. Mean time to healing was 8.2 weeks, with 42% of wounds healed by 12 weeks. The wound volume was reduced by 79.7% over a mean of 12 weeks. According to the authors, noncontact low-frequency ultrasound for treatment of chronic wounds was associated with consistent and substantial wound size reductions, as well as favorable rates of healing. However, the quality of the evidence was limited by small patient numbers and lack of appropriate comparison groups.

Voight et al. (2011) conducted a systematic review and meta-analysis to examine low-frequency (20-30 kHz) ultrasound delivered at either low or high intensity. The objective of the review was to determine whether low-frequency ultrasound used as an adjunctive therapy improves the outcomes of complete healing and reduction of size of chronic lower limb wounds. Eight randomized controlled trials were identified. Three of these trials were unpublished papers presented at conferences. Results demonstrated that early healing (at ≤5 months) in patients with venous stasis and diabetic foot ulcers was favorably influenced by both high- and low-intensity ultrasound delivered at a low frequency–either via contact or noncontact techniques. However, according to the authors, the quality of the evidence is in general of lower quality for both types of ultrasound, and especially for low-frequency low-intensity noncontact ultrasound because of
significant biases. The authors stated that although it appears from the meta-analysis performed that low-frequency low-intensity noncontact ultrasound is more effective at complete healing than standard of care, the quality of the evidence as it relates to biases was poor. The study by Ennis et al. (2005) had a significant protocol violation that resulted in 42 patients being dropped from the study. This protocol violation was a result of an inversion of the treatment distances of the treatment protocol between active and sham devices. Furthermore, in the study by Kavros et al. (2007) it was indicated in the acknowledgments that Celleration (manufacturer of the ultrasound device) supported in the assistance of the manuscript, calling into question the potential quality of the evidence. According to the authors, although there appears to be some clinical benefit with the use of low frequency ultrasound, more and larger size randomized controlled trials should be completed on the longer term clinical effects (i.e., >3 months) for this therapy.

Cullum et al. (2010) assessed whether ultrasound (US) increases the healing of venous leg ulcers by searching several databases for randomized controlled trials (RCTs) comparing US with no US. Two authors independently assessed the search results and selected eligible studies. Details from included studies were summarized using a data extraction sheet, and double-checked. Eight trials were included; all had unclear, or high, risks of bias, with differences in duration of follow-up, and US regimens. Six trials evaluated high frequency US and five of these reported healing at 7 - 8 weeks. Significantly more patients healed with US than without it at 7 - 8 weeks, but later assessments at 12 weeks showed the increased risk of healing with US was no longer statistically significant. One poor-quality study of high-frequency US found no evidence of an effect on healing after three weeks' treatment. Two trials evaluated low frequency US and reported healing at different time points. Both trials reported no evidence of a difference in the proportion of ulcers healed with US compared with no US: both were significantly underpowered. The authors concluded that the trials evaluating US for venous leg ulcers are small, poor-quality and heterogeneous. They state that there is no reliable evidence that US hastens healing of venous ulcers. There is a small amount of weak evidence of increased healing with US, but this requires confirmation in larger, high-quality RCTs. They conclude that there is no evidence of a benefit associated with low frequency US.

Al-Kurdi et al. (2008) reviewed results from 8 small trials (average enrollment 44 patients) with comparator treatments of either sham ultrasound or standard of care. Studies had either a medium or high risk of bias, which indicates a reduction in study validity. Typical study limitations included lack of allocation concealment and failure to report baseline characteristics, randomization methods, and blinding of outcome assessors. The authors concluded that the available evidence suggests that there may be a benefit from ultrasound therapy in healing venous leg ulcers, however due to the poor quality of the studies, these results need to be interpreted with caution.

Several non-randomized studies described the use of MIST Therapy for treating wounds (Honaker et al., 2012; Kavros et al., 2008, Bell et al., 2008). Evidence from these studies is unreliable due to design flaws, such as non-random allocation of treatment and lack of appropriate comparison groups.

In a National Institute for Health and Clinical Excellence (NICE) guidance for MIST Therapy System for the Promotion of Wound Healing in Chronic and Acute Wounds, NICE states that the MIST Therapy System shows potential to enhance the healing of chronic, hard-to-heal, complex wounds, compared with standard methods of wound management. However, the amount and quality of published evidence on the relative effectiveness of the MIST Therapy System is not sufficient, at this time, to support the case for routine adoption of the MIST Therapy System (NICE, 2011).

According to a Hayes Brief for the Mist Therapy System, the studies that were evaluated provided preliminary evidence that, as an adjunct to standard wound care, Mist Therapy improves healing of chronic foot and leg ulcers. However, the quality of the evidence was low due to heterogeneity in the study populations, the lack of control groups in several studies, small sample sizes, differences in treatment protocols, and non-standardized assessment of outcomes. Well-
designed randomized controlled trials with larger study populations are needed to confirm findings on the efficacy of the Mist Therapy System for wound healing, and to evaluate long-term outcomes such as limb salvage, amputation, and quality of life (Hayes 2012).

**Professional Societies**

Association for the Advancement of Wound Care (AAWC): The AAWC released a guideline on the care of pressure ulcers. While noncontact ultrasound therapy was included as a potential second-line treatment if first-line treatments failed to induce wound healing, the strength of the evidence supporting this decision was low (Level C), indicating that there is limited evidence for this technology (AAWC, 2010a).

In a 2010 guideline for venous ulcers, the AAWC states that more evidence is needed to evaluate the use of low frequency ultrasound for venous ulcers (AAWC, 2010b).

American College of Foot and Ankle Surgeons: The American College of Foot and Ankle Surgeons guideline for Diabetic Foot Disorders states that several new ultrasound devices are being used to debride the wound and provide ultrasonic therapy. The guideline also indicates that low-intensity pulsed ultrasound (LIPUS) has also been suggested as a useful adjunct in promoting healing of Charcot fractures. The guideline states that although promising in theory, none of these adjunctive treatments have yet been conclusively proven effective through large prospective multicenter, randomized trials (Frykberg, 2006).

**Additional Search Terms**

Acoustic pressure wound therapy; continuous ultrasonic energy; kilohertz ultrasound therapy; low energy ultrasound wound cleaner; low-intensity ultrasound; nonthermal ultrasound; therapeutic ultrasound; ultrasound therapy; ultrasonic mist debridement; ultrasonic mist therapy

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**


The Mist Therapy System is regulated by the FDA as a Class II device and is classified as an ultrasound wound cleaner. This device was approved via the FDA 510(k) process in April 2004. In May 2005, FDA granted marketing clearance to Celleration for the MIST Therapy System 5.1 with an expanded indication. The approved indication for use is to produce “a low-energy ultrasound-generated mist to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates, and bacteria”. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf. Accessed September 22, 2013.

Another FDA-approved ultrasound wound cleaner is the AR1000 Ultrasonic Wound Therapy System (Arobella Medical LLC) that was approved on January 3, 2007. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062544.pdf. Accessed September 22, 2013.

It is not clear whether this device has been designed to perform the same functions as the Mist Therapy System. See the following Web site for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm (use product code NRB) Accessed September 22, 2013.

In November 2005, the FDA issued a document that outlines the controls applicable to all low-frequency ultrasound devices: Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner. This document provides nonbinding recommendations to address risks associated with these devices (i.e., delayed wound healing, inflammation, thermal damage,
infection, electrical shock) and assure the devices' safety and effectiveness. See the following Web site for more information:

**Additional Products**
Bair Hugger Temperature Management System (Arizant Inc.)

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not cover noncontact normothermic wound therapy as there is insufficient scientific or clinical evidence to consider this device as reasonable and necessary. Refer to the National Coverage Determination (NCD) for Noncontact Normothermic Wound Therapy (NNWT) (270.2)

Medicare does not cover Infrared Therapy Devices for the treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of the skin and/or subcutaneous tissues. Refer to the National Coverage Determination (NCD) for Infrared Therapy Devices (270.6). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Infrared Heating Pad Systems.

Medicare does not have a National Coverage Determination (NCD) for low frequency ultrasound for the treatment of wounds. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Wound Care and Non Covered Services. (Accessed September 25, 2013)

**APPLICABLE CODES**

The 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. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

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<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>97610</td>
<td>Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day</td>
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<tr>
<th>HCPCS Code</th>
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<td>A4639</td>
<td>Replacement pad for infrared heating pad system, each</td>
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<td>A6000</td>
<td>Non-contact wound warming wound cover for use with the non-contact wound warming device and warming card</td>
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<td>E0221</td>
<td>Infrared heating pad system</td>
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<td>E0231</td>
<td>Non-contact wound warming device (temperature control unit, ac adapter and power cord) for use with warming card and wound cover</td>
</tr>
<tr>
<td>E0232</td>
<td>Warming card for use with the non contact wound warming device and non contact wound warming wound cover</td>
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**REFERENCES**


Warming Therapy and Ultrasound Therapy for Wounds: Medical Policy (Effective 01/01/2014)

Association for the Advancement of Wound Care (AAWC). Pressure Ulcer Guideline. October 2010a. Available at http://aawconline.org/professional-resources/resources/

Association for the Advancement of Wound Care (AAWC). Venous Ulcer Guideline. December 2010b. Available at: http://aawconline.org/professional-resources/resources/


**POLICY HISTORY/REVISION INFORMATION**

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| 01/01/2014 | • Updated list of applicable CPT codes to reflect annual code edits (effective 1/1/2014):  
  o Added 97610  
  o Removed 0183T  
• Archived previous policy version 2013T0521F |