

# Noncontact Ultrasound Treatment for Wounds



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## DESCRIPTION

Ultrasound is defined as a mechanical vibration above the upper threshold of human hearing (> 20 KHz). Ultrasound (US) in the MHz range (1-3 MHz) historically, has been used for the treatment of musculoskeletal disorders, primarily by physical therapists. Low-frequency ultrasound is proposed as an adjunct treatment to standard wound care. Although the exact mechanism underlying its clinical effects is not known, therapeutic US has been shown to have a variety of effects at a cellular level including angiogenesis, leukocyte adhesion, growth factor and collagen production, and increases in macrophage responsiveness, fibrinolysis, and nitric oxide levels. More recently, the therapeutic effects of US energy in the kilohertz range have been examined.

A non-contact, low-frequency ultrasound device is intended to provide debridement and cleansing to a wound. The device is held 0.5 to 1.5 cm from the wound and saline is delivered to the wound bed, which purportedly promotes healing through stimulation of cellular activity. Therapy generally consists of three-to-twelve-minute sessions, three times per week.

## **Clinical Context and Therapy Purpose**

The purpose of noncontact low-frequency ultrasound therapy in individuals who have any wound type (acute or nonhealing) is to improve wound healing.

The question addressed in this evidence review is: Does the use of noncontact low-frequency ultrasound therapy improve the net health outcome in patients with any wound type (acute or nonhealing)?

The following PICO was used to select literature to inform this review.

## **Populations**

The relevant population(s) of interest are individuals with any wound type (acute or nonhealing).

## **Interventions**

The therapy being considered is noncontact low-frequency ultrasound therapy.

## **Comparators**

The following therapies/tools/rules/practices are currently being used to make decisions about wound care: Standard wound care.

## **Outcomes**

The general outcomes of interest are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity.

## **Literature**

(2019) Rastogi et al. completed a randomized, double-blind, sham control, single-center study to compare the efficacy of noncontact, low-frequency airborne ultrasound therapy with sham therapy added to standard treatment in patients with neuropathic, clinically infected, or noninfected DFU (wound size  $>2 \text{ cm}^2$ ), Wagner grades 2 and 3. Fifty-eight patients received ultrasound or sham therapy for 28 days dosed daily for 6 days then twice a week for 3 weeks along with standard of care. The duration of wound was  $15.8 \pm 11.2$  weeks and  $12.1 \pm 10.9$  weeks and wound area of  $11.3 \pm 8.2 \text{ cm}^2$  and  $14.8 \pm 13.8 \text{ cm}^2$  ( $P = .507$ ) in the ultrasound and sham groups, respectively. A  $>50\%$  reduction in wound area was observed in 97.1% and 73.1% patients ( $P = .042$ ) in ultrasound and sham groups, respectively. Wound contraction was faster in the first 2 weeks with ultrasound therapy,  $5.3 \text{ cm}^2$ , compared with  $3.0 \text{ cm}^2$  ( $P = .025$ ) with sham treatment. Wound area reduction of  $69.4 \pm 23.2\%$  and  $59.6 \pm 24.9\%$  ( $P = .126$ ) was observed at 4 weeks in the ultrasound and sham groups, respectively. The authors concluded that low-frequency noncontact ultrasound is a useful adjunctive treatment to hasten wound healing in patients with chronic neuropathic DFUs. The limitations include a small sample size, a short follow-up, and single-center study.

(2017) Chang et al. completed a systematic review of current evidence on low-frequency ultrasound debridement in chronic wound healing. In this review, we focus on low-

frequency ultrasound (20-60 kHz) and summarize the findings of 25 recent studies examining ultrasound efficacy. The author's noted ultrasound debridement appears to be most effective when used 3 times a week and has the potential to decrease exudate and slough, decrease patient pain, disperse biofilms, and increase healing in wounds of various etiology. Although current studies are generally of smaller size, the results are promising, and they recommended the testing of low-frequency ultrasound therapy in clinical practice on a larger scale. One of the major limitations of the study, however, was its inability to discern the efficacy of treatment on different types of wound etiology due to the lack of sufficient study numbers for the pooling of data. This limitation also rings true for all other ultrasound modalities due to the lack of well-designed clinical trials. The ultrasound system that was used in this study has not been evaluated separately by other studies. Second, the dosing of the ultrasound was reported to be at 1 MHz, which is considered a high-frequency treatment modality. Our review of the literature suggests that sound frequencies between 20 and 34 kHz yield best results. Finally, the application of such device was only evaluated on venous leg ulcers, which require multimodal care such as compression and offloading as adjuncts to debridement to fully heal their wounds. Ultrasound debridement has a role to play in wound care, but elucidating its mechanism of action, effect on biofilms, and treatment parameters for debridement and postdebridement are part of the current research trajectory. Outcome measures are improving in wound care, and sound clinical research is improving our knowledge in the area of chronic wounds. Chronic wound healing continues to pose great resource and financial stress on health-care systems worldwide. With an aging population and increasing prevalence of chronic health conditions such as diabetes and cardiovascular diseases, treatment protocols addressing associated chronic wounds are urgently needed. Future studies should stratify patients according to comorbidities. Patients with chronic wounds tend to be geriatric patients with a multitude of conditions that needs to be considered to further understand the inherent challenges of their healing trajectory. Nutrition, smoking, and general health also need to be implemented as a part of the study design, as it is an integral part of multifaceted care needed by this population.

(2016) Olyaie et al. completed a randomized controlled trial on the high-frequency and noncontact low-frequency ultrasound therapy for venous ulcer treatment. Ninety (90) outpatients (47 men, 43 women, average age 38.3 [SD 11.5] years) were randomized into the standard care (n = 30), HFU (n = 30), or NCLFU group (n = 30). Standard care included 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. HFU delivers high-intensity (0.5-1 W/cm<sup>2</sup>), high-frequency (1-3 MHz) ultrasound for 5 to 10 minutes; and NCLFU delivers low-intensity (0.1-0.8 W/cm<sup>2</sup>), low-frequency (40 kHz) ultrasound for 4-10 minutes. After 3 months, patients continued to be followed until healed. Wound size, wound pain, and lower leg edema were assessed at baseline and after 2 and 4 months. Data were analyzed using Student's t-test, ANOVA, chi-square, or Fisher's exact test. P <0.05 was considered significant. Initial wound measurements were 9.60 cm<sup>2</sup> (SD 5.54), 9.86 cm<sup>2</sup> (SD 3.95), and 10.01 cm<sup>2</sup> (SD 4.58) for the standard treatment, HFU, and NCLFU groups,

respectively; after 4 months, measurements were 4.28 cm<sup>2</sup> (SD 2.80), 3.23 cm<sup>2</sup> (SD 2.39), and 2.72 cm<sup>2</sup> (SD 2.16), a statically significant difference (P = 0.04). All wounds were healed after an average of 8.50 (SD 2.17), 6.86 (SD 2.04), and 6.65 (SD 1.59) months in the standard treatment, HFU, and NCLFU groups, respectively (P = 0.001). Differences in the amount of edema and pain rating scores were also significant at the 4-month, follow-up visit (P <0.05). Outcomes of both methods of ultrasound therapy were better than standard care alone, and some differences between the two ultrasound therapy groups were observed, but they were not statistically significant. A major limitation of this meta-analysis was the lack of pooled comparisons of NCLFU therapy to optimal wound care alone or to an alternative intervention. Thus, conclusions cannot be drawn about the incremental benefit of NCLFU treatment over optimal wound care alone. The small sample size of this study limit's ability to draw firm conclusions, especially with respect to potential differences between the two methods of ultrasound therapy, because the difference in healing rates between these groups was smaller than those between standard care and the intervention groups. In addition, wound surface in this study was measured by tracing the margins of the open wound and measuring the two maximum perpendicular axes. Although this method is scientifically valid and reliable, use of more precise imaging and histopathological assessment methods may have enhanced study accuracy. In this prospective, comparative clinical study, the effect of standard ulcer care alone was compared with high-frequency ultrasound and noncontact ultrasound therapy in the treatment of VLUs, and the two modes of ultrasound therapy also were compared. The results show wound healing was faster in ultrasound groups in comparison with standard treatment alone; ulcer size, mean degree of pain, and edema decreased more in the ultrasound than in the control groups. Although ulcers in the noncontact ultrasound therapy group had a slightly better response to treatment than those in the high-frequency group, the differences were not statistically significant.

(2015) Gibbons et al. completed a prospective, randomized controlled trail comparing the effects of noncontact, low-frequency ultrasound to standard care in healing venous leg ulcers. Current scientific evidence suggests venous leg ulcers (VLUs) that do not respond to guideline-defined care may have a wound microenvironment that is out of physiological balance. A prospective, randomized, controlled, multicenter trial was conducted to compare percent wound size reduction, proportions healed, pain, and quality-of-life (QOL) outcomes in patients randomized to standard care (SC) alone or SC and 40 kHz noncontact, low-frequency ultrasound (NLFU) treatments 3 times per week for 4 weeks. One hundred, twelve (112) eligible participants with documented venous stasis, a VLU >30 days' duration, measuring 4 cm<sup>2</sup> to 50 cm<sup>2</sup>, and demonstrated arterial flow were enrolled. Of these, 81 reduced <30% in size during the 2-week run-in study phase and were randomized (SC, n = 40; NLFU+SC, n = 41). Median age of participants was 59 years; 83% had multiple complex comorbidities. Index ulcers were 56% recurrent, with a median duration of 10.3 months (range 1 month to 204.5 months) and median ulcer area of 11.0 cm<sup>2</sup> (range 3.7 cm<sup>2</sup>-41.3 cm<sup>2</sup>). All participants received protocol-defined SC compression (30-40 mm Hg), dressings to promote a moist wound environment, and sharp debridement at the bedside for a minimum of 1 time per week. Ulcer measurements were obtained weekly using digital planimetry. Pain and QOL

scores were assessed at baseline and after 4 weeks of treatment using the Visual Analog Scale and the Short Form-36 Health Survey. After 4 weeks of treatment, average wound size reduction was  $61.6\% \pm 28.9$  in the NLFU+SC compared to  $45\% \pm 32.5$  in the SC group ( $P = 0.02$ ). Reductions in median ( $65.7\%$  versus  $44.4\%$ ,  $P = 0.02$ ) and absolute wound area ( $9.0 \text{ cm}^2$  versus  $4.1 \text{ cm}^2$ ,  $P = 0.003$ ) as well as pain scores (from  $3.0$  to  $0.6$  versus  $3.0$  to  $2.4$ ,  $P = 0.01$ ) were also significant. NLFU therapy with guideline defined standard VLU care should be considered for healing VLUs not responding to SC alone. The results of this study warrant further research on barriers to healing and the changes occurring in the tissue of the wound to explore theories that the microenvironment impacts wounds that do not heal despite provision of guideline-defined care.

(2015) Prather et al. completed a prospective randomized controlled trial comparing the effects of noncontact low-frequency ultrasound with standard care in healing split-thickness donor sites. This trial compared the effects of 40-kHz noncontact low-frequency ultrasound (NLFU) in addition to standard care (SC) with SC alone in subjects with split-thickness donor sites of  $20$  to  $200 \text{ cm}^2$ . Standard care consisted of cleansing and moist wound dressings. Outcomes measured were time to healing, defined as absence of drainage and full epithelialization; pain and itching scores; and recidivism rates. The results noted of 33 patients enrolled; 27 were randomized and received a minimum of 4 study treatments. Median age was 49 years, 69% were male, and 84% were burn patients. Comorbidities included hypertension (31%), coronary artery disease (22%), pulmonary disease (38%), anemia (31%), and diabetes (16%). Median donor site area was  $136.0 \text{ cm}^2$ . Noncontact low-frequency ultrasound and SC compared with SC demonstrated a mean time to heal of 12.1 days vs 21.3 days ( $p = 0.04$ ). All NLFU+SC subjects had epithelialized by 4 weeks compared with only 71% in SC. Recidivism rates were 8% for NLFU+SC compared with 45% for SC. Pain scores were reduced and significant differences in itching were observed. The conclusion noted noncontact low-frequency ultrasound and SC compared with SC alone in the treatment of split-thickness donor sites demonstrated significant accelerated healing and reduced pain and itching. Noncontact low-frequency ultrasound subjects experienced a better quality of healing with less incidence of infection and recidivism.

(2015) White et al. completed a randomized controlled trial on non-contact low-frequency ultrasound therapy compared with UK standard of care for venous leg ulcers: a single-center, assessor-blinded, randomized controlled trial. 'Hard-to-heal' wounds are those which fail to heal with standard therapy in an orderly and timely manner and may warrant the use of advanced treatments such as non-contact low-frequency ultrasound (NLFU) therapy. This evaluator-blinded, single-site, randomized controlled trial, compared NLFU in addition to UK standard of care [SOC: (NLFU + SOC)] three times a week, with SOC alone at least once a week. Patients with chronic venous leg ulcers were eligible to participate. All 36 randomized patients completed treatment (17 NLFU + SOC, 19 SOC), and baseline demographics were comparable between groups. NLFU + SOC patients showed a  $-47\%$  (SD: 38%) change in wound area; SOC,  $-39\%$  (38%) change; and difference,  $-7.4\%$  [95% confidence intervals (CIs)  $-33.4$ - $18.6$ ;  $P = 0.565$ ]. The median number of infections per patient was two in both arms of the study and change in

quality of life (QoL) scores was not significant ( $P = 0.490$ ). NLFU + SOC patients reported a substantial mean (SD) reduction in pain score of  $-14.4$  ( $14.9$ ) points, SOC patients' pain scores reduced by  $-5.3$  ( $14.8$ ); the difference was  $-9.1$  ( $P = 0.078$ ). Results demonstrated the importance of high-quality wound care. Outcome measures favored NLFU + SOC over SOC, but the differences were not statistically significant. A larger sample size and longer follow-up may reveal NLFU-related improvements not identified in this study.

(2015) Tricco et al. published an overview of systematic reviews on treatments for complex wounds, which reviewed multiple therapies including ultrasound. Overall, 99 systematic reviews were included after screening 6,200 titles and abstracts and 422 full texts; 54 were systematic reviews with a meta-analysis (including data on over 54,000 patients) and 45 were systematic reviews without a meta-analysis. Overall, 44% of included reviews were rated as being of high quality (AMSTAR score  $\geq 8$ ). Based on data from systematic reviews including a meta-analysis with an AMSTAR score  $\geq 8$ , promising interventions for complex wounds were identified. These included bandages or stockings (multi-layer, high compression) and wound cleansing for venous leg ulcers; four-layer bandages for mixed arterial/venous leg ulcers; biologics, ultrasound, and hydrogel dressings for diabetic leg/foot ulcers; hydrocolloid dressings, electrotherapy, air-fluidized beds, and alternate foam mattresses for pressure ulcers; and silver dressings and ultrasound for unspecified mixed complex wounds. For surgical wound infections, topical negative pressure and vacuum-assisted closure were promising interventions, but this was based on evidence from moderate to low quality systematic reviews. For venous ulcer with ultrasound there was no difference in the time to healing/rate of healing based on low/moderate quality of evidence. A venous ulcer treated with HFUS, LFUS and US reported no difference based on a high quality of evidence. Individuals with a mixed/arterial/venous ulcer treated with US saw an effected wound area/size reduction based on low/moderate quality of evidence. Individuals with a diabetic ulcer treated with US saw no difference in ulcer healing based on a low/moderate quality of evidence. Individuals with a pressure ulcer treated with US saw no difference in the proportion of patient with healed wounds based on a high and low/moderate quality of evidence. Individuals with pressure ulcers treated with US the evidence was uncertain/conflicting evidence/indeterminate for the proportion of patient with healed wound based on low/moderate quality of evidence. The authors concluded numerous interventions can be utilized for patients with varying types of complex wounds, yet few treatments were consistently effective across all outcomes throughout the literature. Clinicians and patients can use our results to tailor effective treatment according to type of complex wound. Network meta-analysis will be of benefit to decision-makers, as it will permit multiple treatment comparisons and ranking of the effectiveness of all interventions.

(2014) Beheshti et al. completed a randomized controlled trail on the comparison of high-frequency and MIST ultrasound therapy for the healing of venous leg ulcers. Ninety patients with VLUs were assigned into the standard treatment, HFU and MIST ultrasound groups. All groups received the standard wound care. In the ultrasound groups, HFU and MIST ultrasound therapy was administered to wounds 3 times per week until the wound

healed. Time of complete wound healing was recorded. Wound size, pain, and edema were assessed at baseline and after 2 and 4 months. Also, patients were instructed to contact our clinic monthly, and recurrence of VLU was recorded for 6 months after complete wound healing. The data was analyzed using a student's t-test, ANOVA, c2, or Fisher's exact test.  $P < 0.05$  was considered significant. The results noted mean time duration of complete wound healing in the first, second and third groups was 8.13 (SD 1.40), 6.10 (SD 1.47) and 5.70 (SD 1.57) months, respectively ( $p < 0.0001$ ). Size of ulcer, mean degree of pain and edema in ultrasound therapy was decreased after the 4-month visit in comparison to the standard-treatment group ( $p = 0.01$ ,  $p < 0.0001$  and  $p < 0.0001$ , respectively). Also, our results don't show any significant differences between groups in the recurrence of VLUs during a 6-month follow up after complete wound healing ( $p = 0.37$ ). The authors concluded the results in the present study show the significant effectiveness of ultrasound therapy in wound healing. Differences between the two ultrasound therapy groups were not statistically significant. Additional work on cost-effective outcomes and planning are greatly needed for the future.

(2011) Voigt et al. Ultrasound as a therapeutic agent in chronic wound healing has been studied extensively. This systematic review and meta-analysis specifically examine low-frequency (20-30 kHz) ultrasound delivered at either low or high intensity. The objective of this 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. PubMed, Cochrane/CENTRAL, technical assessment, relevant wound-related journals, and clinical guidelines were searched along with contacting manufacturers and authors of relevant randomized controlled trials were completed. Searches focused on the use of low-frequency ultrasound in randomized controlled trials. Data were collected via a data collection form and was adjudicated independently via coauthors. Meta-analyses and heterogeneity checks were performed using Mantel-Haenszel and inverse variance (fixed and random effects) statistical methods on studies with similar outcomes (complete healing and percent wound area reduction) over similar time periods. Single study results were reported via the statistical methods used in the study. Eight randomized controlled trials were identified. In patients presenting with either venous stasis or diabetic foot ulcers (Wagner classification 1-3), early healing appears to be facilitated by either low-frequency low-intensity noncontact ultrasound or low-frequency high-intensity contact ultrasound. Results demonstrated that early healing (at  $\leq 5$  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, the quality of the data may be suspect, especially for low-frequency low-intensity noncontact ultrasound because of significant biases.

(2005) Ennis et al. completed a randomized, double-blind controlled trial, multicenter study on ultrasound therapy for recalcitrant diabetic foot ulcers. estimated 15% of patients with diabetes will develop a foot ulcer sometime in their life, making them 30 to 40 times more likely to undergo amputation due to a non-healing foot ulcer than the non-diabetic population. To determine the safety and efficacy of a new, non-contact, kilohertz

ultrasound therapy for the healing of recalcitrant diabetic foot ulcers - as well as to evaluate the impact on total closure and quantitative bacterial cultures and the effect on healing of various levels of sharp/surgical debridement - a randomized, double-blinded, sham-controlled, multicenter study was conducted in hospital-based and private wound care clinics. Patients (55 met criteria for efficacy analysis) received standard of care, which included products that provide a moist environment, offloading diabetic shoes and socks, debridement, wound evaluation, and measurement. The "therapy" was either active 40 KHz ultrasound delivered by a saline mist or a "sham device" which delivered a saline mist without the use of ultrasound. After 12 weeks of care, the proportion of wounds healed (defined as complete epithelialization without drainage) in the active ultrasound therapy device group was significantly higher than that in the sham control group (40.7% versus 14.3%,  $P = 0.0366$ , Fisher's exact test). The ultrasound treatment was easy to use and no difference in the number and type of adverse events between the two treatment groups was noted. Of interest, wounds were debrided at baseline followed by a quantitative culture biopsy. The results of these cultures demonstrated a significant bioburden (greater than  $10^5$ ) in the majority of cases, despite a lack of clinical signs of infection. Compared to control, this therapeutic modality was found to increase the healing rate of recalcitrant, diabetic foot ulcers.

### **Summary of Evidence**

The use of noncontact low -frequency ultrasound (NLFU) has been proposed as supplement to wound therapy. The premise is to promote wound healing through cleansing and debridement of the wound bed. For individuals who have any wound type (acute or nonhealing) who receive noncontact ultrasound therapy plus standard wound care, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. The single double-blinded, sham-controlled randomized trial, which included patients with nonhealing diabetic foot ulcers, had substantial methodologic flaws (e.g., high dropout rate, baseline differences between groups) that limit the validity of the findings. In the remaining studies comprising the evidence base, all but one RCT comparing NLFU with standard wound care reported improved (statistically significant) results on the primary outcome with NLFU. However, these studies also had several methodologic limitations. Complete healing is the most clinically relevant outcome. None of the RCTs evaluating venous leg ulcers reported complete healing as its primary outcome measure, and none had blinded outcome assessment.

One RCT addressed split-thickness graft donor sites, reported on the proportion of patients with complete healing and had blinded outcome assessment. Another limitation of the body of evidence is that some standard of care interventions involved fewer visits than the NLFU intervention, and the differences in intensity of care resulting from this differential in face-to-face contact could partially explain the difference in findings between intervention and control groups. In general, most of the studies did not have many participants, had short follow-up times and had poor study design. US is intended as an adjunct to standard wound care. Therefore, the evidence is needed that demonstrates US plus standard wound care provides superior wound closure outcomes



compared with standard wound care alone. The evidence is insufficient to determine the effects of the technology on net health outcomes.

## **Practice Guidelines and Position Statements**

### **Association for the Advancement of Wound Care (AAWC)**

(2015) The Association for the Advancement of Wound Care (AAWC) published guidelines on the care of venous ulcers.

- Low frequency ultrasound (e.g., 25 kHz at a 35-40 W/cm<sup>2</sup> power intensity) may support healing, reduce pain and improve QOL of non-healing venous or mixed etiology venous ulcers. (CVI=0.619, Moderate SOR) (*Accessed March 2022*)

### **Joint Guidelines**

#### **Society for Vascular Surgery, American Venous Forum, American Podiatric Medical Association**

(2016) The Society for Vascular Surgery in collaboration with the American Podiatric Medical Association published joint guidelines on the management of diabetic foot ulcers.

- The guidelines recommended adjuvant therapy for diabetic foot ulcers that fail to demonstrate more than 50% wound area reduction after 4 weeks of standard wound therapy. The adjunctive wound therapy options listed in the guidelines included negative pressure therapy, biologics (platelet-derived growth factor, living cellular therapy, extracellular matrix products, amniotic membrane products), and hyperbaric oxygen therapy. Ultrasound therapy was not mentioned as a recommended adjuvant option.

(2014) The Society for Vascular Surgery in collaboration with the American Venous Forum published joint guidelines on the management of venous leg ulcers.

- The guidelines recommended adjuvant wound therapy options for venous leg ulcers that fail to demonstrate improvement after 4 to 6 weeks of standard wound therapy (strength of recommendation: grade 1; quality of evidence: level B) but recommended against routine ultrasound therapy for venous leg ulcers (strength of recommendation: grade 2; quality of evidence: level B).

### **Regulatory Status**

The U.S. Food and Drug Administration (FDA) has cleared several devices for marketing through the 510(k) process. *This is not intended to be an all-inclusive list.*

Examples of low-frequency ultrasound devices include, but may not be limited to:

- AR1000 Ultrasonic Wound Therapy System
- AS1000 Ultrasound Wound Therapy System
- Jetox ND
- MIST Therapy™ System
- Qoustic Wound Therapy System™

- SonicOne OR
- SONOCA-180
- SONOCA-185
- UltraMIST®
- VERSAJET II Hydrosurgery System

*Several other devices have been approved as being substantially equivalent to the earlier devices. FDA product code: NRB.*

## PRIOR APPROVAL

Not applicable.

## POLICY

### Related Medical Policy:

- 01.01.20 Non-Powered Negative Pressure Wound Therapy

Use of non-contact, low-frequency ultrasound therapy is considered **investigational** for wound care and all other applications as the evidence is insufficient in demonstrating an impact on improved health outcomes.

## PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 97610 Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care; per day

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## POLICY HISTORY

<b>Date</b>	<b>Reason</b>	<b>Action</b>
March 2022	Annual Review	Policy Revised
March 2021	Annual Review	Policy Renewed
March 2020	Annual Review	Policy Revised
March 2019	Annual Review	Policy Renewed
March 2018	Annual Review	Policy Revised
March 2017	Annual Review	Policy Revised
March 2016	Annual Review	Policy Renewed
April 2015	Annual Review	Policy Renewed
May 2014		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield  
 Medical Policy Analyst  
 PO Box 9232  
 Des Moines, IA 50306-9232

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