



# Noncontact Warming Therapy, Ultrasound Therapy, and Fluorescence Imaging for Wounds

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## Application

### UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

### UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

## Coverage Rationale

Warming therapy or noncontact normothermic wound therapy (NNWT) and low frequency ultrasound therapy are unproven and not medically necessary for treating wounds due to insufficient evidence of efficacy.

Noncontact real-time fluorescence wound imaging for bacterial presence is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description   |
|----------|---|
| 0598T    | Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (e.g., lower extremity)   |
| 0599T    | Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (e.g., upper extremity) (List separately in addition to code for primary procedure) |
| 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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| HCPCS Code | Description   |
|------------|---|
| A6000      | Noncontact wound-warming wound cover for use with the noncontact wound-warming device and warming card                          |
| E0231      | Noncontact wound-warming device (temperature control unit, AC adapter and power cord) for use with warming card and wound cover |
| E0232      | Warming card for use with the noncontact wound warming device and noncontact wound warming-wound cover                          |

## Description of Services

Warming therapy or noncontact normothermic wound therapy (NNWT) 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.

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.

The MIST Therapy® System is a noncontact, low-frequency ultrasound debridement device that has been developed to promote healing of chronic wounds by removing yellow slough, tissue exudates, fibrin, and bacteria from the wound surface. The main components of the MIST Therapy® System are an ultrasound generator; a handheld ultrasound transducer; and a single-use, disposable applicator with a bottle reservoir for sterile saline. The transducer tip vibrates 40,000 times per second to generate ultrasound waves at 40 kilohertz (kHz) that are carried to the wound via a saline mist. In addition to wound cleaning, ultrasonic energy has been proposed as a means of stimulating angiogenesis, growth factor production, and other cellular activities that contribute to wound healing.

MolecuLight i:X® is a handheld fluorescence imaging device for real-time detection of bacteria in wounds; the violet light illumination captures and documents the presence of bacteria in the wound and surrounding areas. The device provides clinicians with information about the fluorescent characteristics of a wound to assist them in making improved diagnostic and treatment decisions.

## Clinical Evidence

### Warming Therapy

The safety and efficacy of warming therapy or noncontact normothermic wound therapy (NNWT) 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, and short follow-up times.

Yue et al. (2018) conducted a systematic review to assess the effects of local warming therapy (LWT) in treating chronic wounds. The inclusion criteria included randomized controlled trials (RCTs) that recruited people with chronic wound(s)

(pressure ulcers, venous leg ulcers, arterial ulcers, diabetic foot ulcers (DFUs) and arterial ulcers) comparing the effects of LWT with standard wound care or other wound-healing interventions. Primary outcomes included time to healing assessed using appropriate survival analysis, proportion of people with DFUs undergoing amputation of the lower limb at any level, including single toes, and proportion of wounds with complete healing. Secondary outcomes consisted of change in wound size, with change expressed as absolute change or relative change; healing rate; quality of life measured by a validated scale. No RCTs comparing the effects of LWT with standard wound care or other wound-healing interventions amongst people with chronic wound(s) were found. It was therefore not possible to undertake a meta-analysis. The authors concluded that this review highlights the lack of robust evidence for the use of LWT in the treatment of chronic wounds. Thus, no definitive conclusions regarding using LWT for treating chronic wounds can be drawn from this review.

Thomas et al. (2005) conducted a randomized controlled comparative study on forty-one patients with a stage 3 or stage 4 truncal pressure ulcer > 1.0 cm<sup>2</sup>. The experimental group was randomized to a radiant-heat dressing device and the control group was randomized to a hydrocolloid dressing, with or without a calcium alginate filler. They were followed until healed or for 12 weeks. Eight patients (57%) in the experimental group had complete healing of their pressure ulcer compared with 7 patients (44%) with complete healing in the control group ( $p = .46$ ). The authors concluded that although a 13% difference in healing rate between the two arms of the study was found, this difference was not statistically significant. This was a small sample size study.

A randomized pilot study was performed by Karr (2003) to evaluate the use of NNWT in the treatment of wounds associated with osteomyelitis. The study consisted of two arms. The control arm ( $n = 11$ ) received standard wound care, which resulted in complete ulcer healing at an average of 127 days. The treatment arm ( $n = 5$ ) received NNWT, which resulted in complete ulcer healing at an average of 59 days, or 54% faster than in the control arm. The authors concluded that although NNWT is not a direct treatment for osteomyelitis, this new treatment option results in accelerated healing of wounds associated with osteomyelitis. However, this difference did not reach statistical significance, and median wound healing times did not differ between groups.

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<sup>®</sup> device. The Warm-Up<sup>®</sup> 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.

## Low Frequency Ultrasound

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

Chen et al. (2023) performed a meta-analysis to evaluate the effect of low-frequency ultrasound as an added treatment for chronic wounds. A systematic literature search, up to May 2022, was performed and 838 subjects with chronic wounds at the baseline of the studies; 412 of them were using the low-frequency ultrasound (225 low-frequency high-intensity contact ultrasound for DFUs, and 187 low-frequency low-intensity non-contact ultrasound for a venous leg wound ulcers), and 426 were using standard care (233 sharp debridement for DFUs and 193 sham treatments for venous leg wound ulcers). Odds ratio (OR), and mean difference (MD) with 95% confidence intervals (CIs) were calculated to assess the effect of low-frequency ultrasound as an added treatment for chronic wounds using the dichotomous, and contentious methods with a random or fixed-effect model. The low-frequency high-intensity contact ultrasound for DFUs had lower non-healed DFUs at  $\geq 3$  months (OR, 0.37; 95% CI, 0.24-0.56,  $p < .001$ ), a higher percentage of DFUs area reduction (MD, 17.18; 95% CI, 6.62-27.85,  $p = .002$ ) compared with sharp debridement for DFUs. The authors concluded that the low-frequency low-intensity non-contact ultrasound for a venous leg wound ulcers had a lower non-healed venous leg wound ulcers at  $\geq 3$  months (OR, 0.31; 95% CI, 0.15-0.62,  $p = .001$ ), and higher percentage venous leg wound ulcers area reduction (MD, 18.96; 95% CI, 2.36-35.57,  $p = .03$ ) compared with sham treatments for a venous leg wound ulcer. The low-frequency ultrasound as an added treatment for DFUs and venous leg wound ulcers had lower non-healed chronic wound ulcers at  $\geq 3$  months, a higher percentage of chronic wound ulcers area reduction compared with standard care. The authors also stated analysis of outcomes should be with caution because of the low sample size of 7 out of 13 studies in the meta-analysis and a low number of studies in certain comparisons. Along with small sample size, additional limitations include possible bias induced by incomplete details including age, gender, and nutritional status of subjects, inclusion of observational studies, as well as missing data from unpublished articles. The findings of this study need to be validated by well-designed studies. (Studies by Olyaie et al. (2013), Gibbons et al. (2015), Murphy et al. (2018), and Rastogi et al. (2019), which were previously cited in this policy, are included in this systematic and meta-analysis review).

Flores-Escobar et al. (2022) conducted a systematic review and meta-analysis of RCTs to investigate the effect of ultrasound-assisted wound (UAW) debridement in patients with DFUs. All selected studies were evaluated using the Cochrane risk of bias tool to assess the risk of bias for randomized controlled trials. A total of 8 RCTs met inclusion criteria, with 263 participants. Concerning the healing rate comparing UAW versus the control group, a meta-analysis estimated the pooled OR at 2.22 (95% CI 0.96–5.11,  $p = 0.06$ ), favoring UAW debridement, with low heterogeneity ( $x^2 = 7.47$ ,  $df = 5$ ,  $p = 0.19$ ,  $I^2 = 33\%$ ). Time to healing was similar in both groups: UAW group ( $14.25 \pm 10.10$  weeks) versus the control group ( $13.38 \pm 1.99$  weeks,  $p = 0.87$ ). Wound area reduction was greater in the UAW debridement group ( $74.58\% \pm 19.21\%$ ) than in the control group ( $56.86\% \pm 25.09\%$ ), although no differences were observed between them ( $p = 0.24$ ). UAW debridement showed higher healing rates, a greater percentage of wound area reduction, and similar healing times when compared with placebo (sham device) and standard of care in patients with DFUs, although no statistical differences were observed between groups. The main limitation of this systematic review with meta-analysis is the small sample size of the RCTs included, which limits the generalizability of the results. Another important limitation is heterogeneity between the different RCTs, in terms of the clinical characteristics of the DFUs included (depth, infection, or ischemia), study follow-up time, time of application, and frequency of application associated with the type of ultrasound used (contact or non-contact). Finally, the lack of certain information in the studies is another limitation in evaluating some variables since it prevents the inclusion of some studies in our meta-analysis. Further clinical trials with low risk of bias, using control groups, with clear randomization and blinding of results is needed to determine the clinical relevance of these findings. (Study by Rastogi et al. (2019), which were previously cited in this policy, are included in this systematic review and meta-analysis review).

Messa et al. (2019) conducted a retrospective case series for patients undergoing lower extremity wound treatment with direct, low-frequency (22.5 kHz), high-intensity ( $\sim 60 \text{ W/cm}^2$ ) ultrasonic debridement. The study included 82 wounds in 51 patients. Primary outcomes included wound healing assessed by the percentage of wound reduction up to 180 days post ultrasound treatment, readmission rates and reoperation rates. Average wound age at initial presentation was 1013 days with an average wound size of 9.0cm x 7.4cm. At 180-days post-debridement, 60% of wounds had completely healed. Readmission for wound healing (70%) was primarily for further debridement (41%). Wound infection (30%) was the most common readmission for wound complications (30%). Reoperations primarily consisted of treatments for further wound healing 96%. The authors concluded that the use of direct, low-frequency, high-intensity, ultrasonic debridement is a safe and reliable adjunctive therapy for the management of wounds. The study had a small sample size and no comparison group.

Bekara et al. (2017) conducted a systematic review to describe, evaluate, and compare three recently developed methods for the management of chronic wounds: hydrosurgery (Versajet), ultrasound therapy (the MIST therapy device), or plasma-mediated bipolar radio-frequency ablation therapy (Coblation). In January 2016, an electronic database search was conducted of MEDLINE, PubMed Central, and Embase for articles concerning these three innovative methods for the management of chronic wounds. A total of 389 references were identified, and 15 articles were included. The authors extracted data regarding the number and age of patients, indications, operating time, number of procedures, costs, wound healing time, decrease in exudation, perioperative blood loss, bacterial load, and the occurrence of complications. The 15 articles included studies that involved 563 patients who underwent hydrosurgery (7 studies), ultrasound therapy (6 studies), or Coblation (2 studies). Six RCTs were included that compared the use of a scalpel or curette to hydrosurgery (2 studies) or ultrasound therapy (6 studies). The authors concluded that hydrosurgery, in addition to being a very precise and selective tool, allowed significantly faster debridement. Ultrasound therapy provided a significant reduction of exudation and improved the wound healing time. However, no comparative study dedicated to Coblation was identified. The authors concluded that despite the obvious clinical interest on this topic, their review of the current literature revealed a lack of prospective randomized studies comparing these devices with each other or with standard techniques, particularly for Coblation and hydrosurgery.

Cullum and Liu (2017) performed a systematic review to investigate whether ultrasound helps to heal or improve the symptoms of venous leg ulcers. Eleven RCTs involving a total of 969 participants were found. Eight studies compared ultrasound with use of no ultrasound for venous leg ulcers and the other three compared ultrasound with sham ultrasound. Seven out of the eleven studies were at high risk of bias, one study was at low risk of bias and bias could not be determine in three studies due to poor reporting. The authors found that the results of one study (337 participants) suggested that high-frequency ultrasound may be associated with more adverse events such as pain and skin redness (moderate quality evidence). The two studies that evaluated low-frequency ultrasound did not report whether participants experienced side effects. It is also uncertain whether either high- or low frequency ultrasound affects participants' quality of life. The outcomes of adverse effects, quality of life and cost were not reported for low-frequency ultrasound treatment. The authors concluded that it is uncertain whether therapeutic ultrasound (either high or low frequency) improves the healing of venous leg ulcers. They rated most of the evidence as low or

very low quality due to risk of bias and imprecision. Most of the studies did not have many participants, had short follow-up times, and had poor study design.

A systematic review to examine ultrasound (US) for the treatment of chronic wounds, therapeutic efficacies, and clinical considerations was conducted by Alkahtani et al. (2017). Forty studies were included. The authors found that the evidence for the effectiveness of US for pressure ulcers is limited. RCTs showed no significant differences between the treatment groups. Low-frequency US techniques have been used in combination with standard wound care medications for treatment of purulent wounds. The findings of these studies showed the therapeutic effectiveness of US technique as an adjunctive or alternative treatment for purulent wound. US to treat diabetic wound studies had a lack of strong evidence due to insufficient sample size, short follow-up period, non-random allocation to treatment arms, non-blinded outcomes evaluation, poor description of control, and concurrent interventions. The review found that therapeutic efficacy of the low-frequency low-dose US technique in chronic venous leg ulcers can shorten the healing period of open wound. The authors concluded that although early studies have been relatively promising, the main challenge for developing US-based techniques as standard treatment options for different wounds is defining an exact dose-response for each wound. Further controlled trials with larger sample sizes are necessary.

Chang et al. (2017) performed a systematic review of current clinical evidence on the use of low-frequency (20-60 kHz) ultrasound in chronic wounds. Twenty-five studies were included. The authors found the current body of evidence supports the use of low frequency ultrasound as adjunctive therapy at least 3 times a week in the treatment of chronic wounds. The majority (21 of 25 studies) of the evidence is limited by study design, representing mostly level 3 to level 5 evidence. One of the major limitations of the study 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. More well-designed clinical trials are needed.

Wagner-Cox et al. (2017) performed a retrospective study to examine the effect of noncontact low-frequency ultrasound (NLFU) on deep tissue pressure injury (DTPI), both hospital-acquired and those present on admission (POA). Medical records from 44 adult patients with a DTPI treated with NLFU were reviewed; 22 had a hospital acquired DTPI (HADTPI) and 22 had DTPI POA. Data were collected from the medical records including demographic and relevant clinical characteristics, DTPI measurements, and DTPI evolution/resolution. All patients with HADTPI and DTPI POA treated with NLFU exhibited a statistically significant decrease in injury size from initiation to discontinuation of NLFU therapy (24.6 cm vs 14.4 cm). No statistically significant difference in wound resolution was found between HADTPI versus DTPI POA (27% vs 18%). Mean size of both HADTPI and DTPI POA decreased significantly from 15.9 to 13.4 cm. by NLFU therapy. Wounds were classified as resolved at completion of treatment in 23% (10 out of 44) of all treated patients. Of all patients with the potential to be resolved (not discharged early or expired) 63% (10 out of 16) had wounds classified as resolved. The authors concluded that study findings suggest that NLFU is a viable and promising treatment option for both HADTPI and DTPI POA. The findings are limited by lack of control group receiving a different treatment. Future studies are needed to confirm these results and to examine efficacy and feasibility of DTPI across care settings.

White et al. (2016) compared non-contact low-frequency ultrasound (NLFU) in addition to standard of care (SOC) 3 times a week, with SOC alone at least once-weekly in a single-site, blinded randomized control trial. Thirty-six randomized patients with chronic venous ulcers completed treatment (17 NLFU + SOC, 19 SOC). NLFU plus SOC patients showed a -47 % change in wound area; SOC, -39 % change; with a difference of -7.4 % (p = 0.6). The median number of infections per patient was two in both groups and the change in quality of life (QoL) scores were not significant. Non-contact low-frequency ultrasound plus SOC patients reported a substantial mean reduction in pain score of -14.4 points, SOC patients' pain scores reduced by -5.3; with a difference of -9.1 (p = 0.08). The authors concluded that the results demonstrated the importance of high-quality wound care and that outcome measures favored NLFU + SOC over SOC, but the differences were not statistically significant. The significance of this study is limited by small sample size and a short follow-up period.

In a 2014 study by Beheshti and colleagues, 90 participants with venous leg ulcers were randomized to receive standard treatment (consisting of compression therapy) and high frequency ultrasound, standard treatment and MIST<sup>®</sup> ultrasound therapy, or standard treatment alone. Study endpoints included the mean time duration of wound healing, edema, pain, size of ulcers and recurrence rate of the ulcers. In the two ultrasound groups, therapy was administered 3 times per week until the wound healed. Wound size, pain and edema were assessed at baseline and after 2 and 4 months. Mean time duration of complete wound healing was 8.13 months in the standard treatment group, 6.10 months in the high frequency ultrasound group, and 5.70 months in the MIST ultrasound group. Edema was mild to severe in all groups at the first visit following treatment. After 4 months, the edema was less in both ultrasound groups when compared to the standard treatment group; however the difference of edema between the two ultrasound groups was not significant. Pain degree was also found to be

decreased in the ultrasound groups compared to the standard treatment group, but again no significant differences were found between the two ultrasound groups. Six months following treatment, the venous leg ulcers recurred in 4 participants in the standard treatment group, and 2 participants in each of the ultrasound groups. Although the authors noted improvement in edema, a decrease in pain and less recurrence in the ultrasound groups when compared to compression therapy, there were no significant differences between the high frequency ultrasound and the MIST ultrasound groups. The findings are limited by lack of masking to group assignment. Further studies with longer follow-up are needed.

Yao et al. (2014) conducted a randomized clinical pilot 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 patients with DFU, 2 (16.7%) with type 1 and 10 (83.3%) with type 2 diabetes, with an average age of  $58 \pm 10$  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 demonstrated that NCLF-US is an effective in treating neuropathic DFUs through at least in part, inhibiting pro-inflammatory cytokines in chronic wound and improving tissue regeneration. 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.

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 multicenter, two arm randomized controlled trial. The study included 337 patients with at least one venous leg ulcer of  $> 6$  months' duration or  $> 5$  cm<sup>2</sup> area and an ankle brachial pressure index of  $\geq 0.8$ . 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.

## Noncontact Real-Time Fluorescence Wound Imaging

The safety and efficacy of handheld, noncontact imaging devices that can visualize fluorescent bacteria and measure wound surface area in real-time has not been established in the published literature. Despite FDA approval of the MolecuLight i:Xdevice, additional robust clinical studies need to be completed to determine the safety and efficacy of this device. While some evidence exists for the predictive characteristics of the method compared to conventional wound cultures, the clinical utility of the method in improving care and patients' outcomes is unclear.

Armstrong et al. (2023) conducted a post-hoc multicenter clinical trial analysis of 138 DFUs to evaluate fluorescence (FL)-imaging role in detecting biofilm-encased and planktonic bacteria in wounds at high loads. The sensitivity and specificity of clinical assessment and FL-imaging were compared across bacterial loads of concern (104 –109 CFU/g). Quantitative tissue culture confirmed the total loads. Bacterial presence was confirmed in 131/138 ulcers. Of these, 93.9% had loads  $> 104$  CFU/g. In those wounds, symptoms of infection were largely absent and did not correlate with, or increase proportionately with, bacterial loads at any threshold. FL-imaging increased sensitivity for the detection of bacteria across loads 104 –109 ( $p < .0001$ ), peaking at 92.6% for  $> 108$  CFU/g. Imaging further showed that 84.2% of ulcers contained high loads in the peri-wound region. The authors anticipate that the definition of chronic inhibitory bacterial load (CIBL) will spark a paradigm shift in DFU wound assessment and management that encourages and enables earlier intervention along the bacterial-infection continuum, thereby preventing sequelae of infection and supporting improved DFU outcomes. The authors concluded that FL-imaging of bacterial burden has potential for facilitating early bacterial intervention, monitoring treatment effectiveness during and after debridement, aiding antimicrobial stewardship to limit antibiotic and antimicrobial dressing prescriptions, and improving wound healing outcomes. Clinicians had limited experience using FL-imaging in a clinical context before the study; this may have lowered the sensitivity of FL-imaging to detect bacteria at loads  $> 104$  CFU/g (sensitivity previously reported to range from 72%

to 100%). Limitations of the imaging technology described include a limited (1.5 mm) depth of excitation and the inability to detect non-porphyrin-producing bacteria, including all species from the Streptococcus, Enterococcus, and Finegoldia genres, although these rarely occur mono-microbially in chronic wounds. Additional limitations are that this study focused primarily on high bacterial load as a contributor to wound pathogenicity, but there are additional systemic factors which delay DFU healing and increase infection risk (e.g., peripheral artery disease, poor glycemic control, neuropathy). As the number of datapoints for each bacterial load threshold ranges from n = 14 to 34, these results should be interpreted with caution. The clinical utility of the technology to improve patient-centered outcomes was not assessed in this study. Finally, there is risk of bias and a potential conflict of interest as this clinical trial was funded by MolecuLight, Inc.

A clinical evidence assessment by ECRI suggests the evidence for the use of the MolecuLight i:X Fluorescence Imaging System is inconclusive. While the evidence might suggest the MolecuLight i:X Fluorescence Imaging System may be helpful for identification of wounds with bacterial loads, additional RCTs are needed to confirm the safety and efficacy of the device (ECRI 2021).

Le et al. (2020, included in ECRI report above), conducted a prospective multicenter observational study on the use of MolecuLight i:X for 350 participants. Wounds underwent clinical signs and symptoms (CSS) assessment using the International Wound Infection Institute (IWII) checklist immediately followed by fluorescent imaging with the MolecuLight device. CSS assessment missed approximately 85% of bacterial loads that were greater than  $10^4$  CFU/g which can be indicative of infection. The authors found the use of the MolecuLight device resulted in higher sensitivity and accuracy of the detection of the bacteria. Limitations of the study included underreporting of bacteria diversity with the culture analysis, limited experience by clinicians in using the MolecuLight device and funding of the study by MolecuLight, Inc. The authors recommend the MolecuLight device be used in combination with CSS assessment and that evidence from larger longitudinal studies would be beneficial. The clinical utility of the technology to improve patient-centered outcomes was not assessed in this study.

Farhan and Jeffery (2020) conducted a single-center observational study to assess the MolecuLight i:X device for efficacy in pediatric burn wounds and the overall feasibility of the device. Ten patients were recruited, and the device was utilized on sixteen different wounds to assess for the presence or absence of clinical signs and symptoms of infection; swabs were obtained to confirm the findings. The authors found the device demonstrated ability to visually identify significant bacterial growth and high compliance for use of the device. The authors conclude that these findings may pave the way for including bacterial fluorescence imaging use into the pediatric burn population. The clinical utility of the technology to improve patient-centered outcomes was however not assessed in this study.

Chew and associates (2020) stated that early diagnosis of wound infections is crucial as they have been shown to increase patient morbidity and mortality. These researchers examined the use of MolecuLight i:X to identify infections in acute open wounds in hand trauma. In a prospective cohort study, data was collected from patients who attended the hand trauma unit over a 4-week period before having surgery. Wounds were inspected for clinical signs of infection and auto-fluorescence images were taken using the MolecuLight i:X device. Wound swabs were taken, and results interpreted according to report by microbiologist. Auto-fluorescence images were interpreted by a clinician blinded to the microbiology results. A total of 31 patients were included and data collected from 35 wounds; 3 wounds (8.6 %) showed positive clinical signs of infection, 3 (8.6 %) were positive on auto-fluorescence imaging and 2 (5.7 %) of wound swab samples were positive for significant infection. Auto-fluorescence imaging correlated with clinical signs and wound swab results for 34 wounds (97.1 %). In 1 case, the clinical assessment and auto-fluorescence imaging showed positive signs of infection, but the wound swabs were negative. The authors concluded that auto-fluorescence imaging in acute open wounds may be useful to provide real-time confirmation of bacterial infection and thus guide management.

A pilot study performed by Pijpe et al. (2019) compared the detection of bacteria in burn wounds between a bacterial fluorescence imaging device MolecuLight i:X and standard microbiological swabs. A total of 14 patients with 20 wounds participated in the study. Wounds were swabbed three times: once with a standard swab, once with a high-fluorescent area swab, and a finally with a non-fluorescent (nF) area swab. Proportion agreement of the microbiological results was calculated and the accuracy of the device to detect relevant bacteria was assessed. The diagnostic accuracy of the bacterial fluorescence imaging device to detect relevant bacteria in burn wounds was moderate and the reliability was equal to standard swabbing. Further research in larger sample sizes is needed for safety and efficacy of the fluorescence imaging device.

Raizman et al. (2019) conducted a prospective comparative study aimed to assess the accuracy, clinical incorporation and documentation capabilities of a handheld bacterial fluorescence imaging device (MolecuLight i:X). In a clinical trial, trained

clinicians digitally measured and captured fluorescence images to assess for presence moderate to heavy loads of bacteria in 50 wounds. The results showed wound measurement was accurate 95%. A positive signal for bacterial fluorescence was demonstrated 72%. Sampling of wounds was found to under-report bacterial loads relative to fluorescence-guided curettage samples.

In a pilot study, Serena et al. (2019) evaluated 19 wounds for diagnostic accuracy of wound bacteria when bacterial fluorescence imaging (MolecuLight i:X) was used in combination with clinical evaluation of signs and symptoms (CSS). CCS criteria for wounds to determine the presence or absence of moderate-to-heavy bacterial loads was done using the NERDS (non-healing, exudate, red and bleeding surface or granulation tissue, debris and smell) and STONEES (size, temperature, osteomyelitis, new areas, exudate, erythema, and smell) method. Then fluorescence images of the wound were acquired along with determination of bacterial presence or absence. Biopsies were obtained under local anesthetic and sent to lab for confirmation; all lab staff was blinded to the wound's assessment outcomes. 4 out the 19 patients (21%) were identified as positive (for moderate-to-heavy bacterial loads) based on clinical signs and symptoms alone. The use of fluorescence imaging in combination with CSS assessment led to 2.5–3.2-fold improvements in reported diagnostic accuracy measures as compared with CSS assessment alone. The authors concluded the data in this pilot study suggests that current standard of care assessment for wounds fails to identify many wounds with moderate-to-heavy bacterial loads, leaving patients with undetected and untreated bacteria. The addition of bacterial fluorescence imaging improved sensitivity and accuracy of assessments for detecting moderate-to-heavy bacterial loads. Limitations of this study included small sample size thus not statistically significant and lack of follow-up. Future larger sample studies are needed.

In a prospective observational study, Hurley et al. (2019) swabbed 43 wounds from 33 patients. The authors wanted to establish the accuracy of the wound imaging device at detecting bacteria. All data was collected in the outpatient wound care clinic setting. Patients over 18 were recruited with a variety of wounds; participants on antibiotics for wound infection were excluded. Images from the wounds were captured with the handheld fluorescent device; upon visualization of bacteria, areas of red or cyan fluorescence indicating bacteria were swabbed and sent to the lab for culture and sensitivity testing. Of the swabs taken, 95.4% were positive for bacteria growth and nine different species of bacteria were identified. Limitations included device incompatibility for wounds with active bleeding, dressings that contained silver (a potent antimicrobial) and sample size. Despite these limitations, the authors concluded the device as safe, effective and accurate for use. Further research should be directed to its application in other environments such as preoperative and perioperative settings.

Twenty patients with burn wounds were photographed under both a standard light and violet light illumination to compare presentations of obvious infection signs and symptoms. Microbiology swab samples were obtained; the fluorescence images were used to guide swabs to where the bacteria were collecting. Four patients did not have bacterial contamination based on their images and swab results, sixteen patients showed growth of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, or other bacteria and nine of the patients, by definition, had infections. Blumenthal and Jeffery (2018) found the prospective comparative study to show the efficacy of the MolecuLight i:X is evident due to the microbiology results correlating to the images. With these early results and guidance of swab samples, the MolecuLight i:X may be able to detect bacterial load before an infection and subsequent graft failure, thereby shortening lengths of hospital stay and improving overall healing. Further research with well-designed studies is needed to test the device in terms of being an early intervention tool.

Rennie et al. (2017, included in the ECRI report above) conducted a prospective cohort study where 60 lower chronic limb wounds were imaged for bacterial fluorescence using the MolecuLight i:X imaging device. Point-of-care bacterial fluorescence imaging illuminates a wound with 405nm light, triggering bacteria to produce red fluorescence and enabling real-time bacterial concentration. Regions positive for red fluorescence were sampled by either biopsy or curettage for bacterial presence and analysis. The authors found fluorescence imaging of wounds offers clinicians' real-time information on the wound's bacteria which can potentially influence treatment decisions.

For information on current clinical trials studying the use of MolecuLight i:X and bacterial growth, go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). (Accessed April 17, 2023)

## Clinical Practice Guidelines

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

In 2015, members of the Association for the Advancement of Wound Care (AAWC), Wound Healing Society, and the Canadian Association for Enterostomal Therapy formed the International Consolidated Guidelines Taskforce to update the AAWC Venous

Ulcer Guidelines to the collaborative, intersociety, endorsed International Consolidated Venous Ulcer Guideline. This clinical practice guideline contains systematically developed recommendations intended to optimize patient care and assist physicians and other health care practitioners and patients to make decisions about appropriate health care for venous ulcer (VU) clinical care (Couch et al., 2017).

Recommendations include the following:

- Low frequency ultrasound may support healing, reduce pain, and improve QOL of non-healing venous or mixed etiology venous ulcers.
- Use ultrasound stimulation in combination with adequate patient-appropriate compression and moisture-retentive dressings to add possible VU healing benefit, but be aware that limited evidence supports cost effectiveness, enduring benefit, or parameters of application.
- Warming therapy has insufficient evidence of healing efficacy to inform VU management decisions about its use as an adjunct to optimal patient-appropriate compression and moisture-retentive dressings.

In an updated 2015 guideline for venous ulcers (VU), the AAWC indicates that low frequency ultrasound may support healing, reduce pain, and improve QOL of non-healing venous or mixed etiology venous ulcers (moderate strength of rating). The AAWC also indicates that ultrasound stimulation may be used in combination with adequate patient-appropriate compression and moisture-retentive dressings to add possible VU healing benefit but be aware that limited evidence supports enduring benefit or parameters of application (AAWC, 2015).

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, 2010).

### ***American Podiatric Medical Association***

The American Podiatric Medical Association in collaboration with the Society for Vascular Surgery and the Society for Vascular Medicine developed a 2016 clinical practice guideline for the management of diabetic foot. Their recommendations do not include warming therapy, noncontact normothermic wound therapy (NNWT) or low frequency ultrasound for the treatment of wounds (Hingorani et al. 2016).

### ***National Institute for Health and Care Excellence (NICE)***

A National Institute for Health and Care Excellence (NICE) Medtech innovation briefing [MIB212] concluded that there is limited evidence to show whether MolecuLight i:X reduces wound closure time or improves antibiotic stewardship (2020).

The National Institute for Health and Care Excellence (NICE) guideline for diabetic foot problems prevention and management recommends one or more of the following as standard care for treating DFUs: offloading; control of foot infection; control of ischemia; wound debridement; and wound dressings. NICE recommends that negative pressure wound therapy should be considered after surgical debridement for DFUs, on the advice of the multidisciplinary foot care service. Dermal or skin substitutes as an adjunct to standard care can be considered when treating DFUs, only when healing has not progressed, and on the advice of the multidisciplinary foot care service (NICE, 2019).

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, Reaffirmed June 2016).

## **U.S. Food and Drug Administration (FDA)**

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Warm-Up® Active Wound Therapy (Augustine Medical, Inc.) received 510(k) approval from the FDA on March 28, 1997, as a wound and burn occlusive heated dressing. Refer to the following website for more information (use product code MSA): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. (Accessed April 17, 2023)

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." In 2014 the FDA approved the UltraMIST® System (K140782), a smaller, sleeker, and user-friendly design. Refer to the following website for more information:  
[http://www.accessdata.fda.gov/cdrh\\_docs/pdf5/K050129.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf5/K050129.pdf). (Accessed April 17, 2023)

Refer to the following website for additional devices (use product code NRB):  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed April 17, 2023)

The U.S. Food and Drug Administration (FDA) cleared The MolecuLight i:X® device under its 510(k) premarket notification process as substantially equivalent to predicate devices. For additional information refer to the following:  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/K191371.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191371.pdf). (Accessed April 17, 2023).

Refer to the following website for additional devices (use product code QJF or FXN):  
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed April 17, 2023)

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## Policy History/Revision Information

| Date       | Summary of Changes   |
|------------|--|
| 10/01/2023 | <p><b>Application</b><br/><b>Individual Exchange Plans</b></p> <ul style="list-style-type: none"> <li>Removed language indicating this Medical Policy does not apply to Individual Exchange benefit plans in the states of Massachusetts, Nevada, and New York</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Archived previous policy version 2023T0521T</li> </ul> |

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). (Accessed April 17, 2023)

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.