Policy Number	**DME101.050**
Policy Effective Date	**08/15/2024**
Policy End Date	**12/31/2025**

Noncontact Warming Therapy and Fluorescence Imaging for Wounds

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Related Policies (if applicable)
DME101.044 Noncontact Ultrasound Treatment for Wounds

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

Use of noncontact normothermic wound therapy (NNWT) or a noncontact wound warming device, either as a primary intervention or as an adjunct to other wound therapies, **is considered experimental, investigational and/or unproven.**

Noncontact real-time fluorescence wound imaging (e.g., MolecuLight) for bacterial presence **is considered experimental, investigational and/or unproven** for all indications.

Policy Guidelines

None.

Description

An optimal environment for wound healing is thought to include a moist normothermic (normal body temperature) environment that functions in part to enhance the subcutaneous oxygen tension and to increase the blood flow to the wound. Warm-up Wound Therapy® is a device approved for marketing by the United States Food and Drug Administration (FDA) that attempts to create this normothermic environment. The device includes a noncontact bandage and a warming unit, designed to maintain 100% relative humidity and to produce normothermia in the wound and surrounding tissues. The bandage is composed of a sterile foam collar that adheres to the periwound skin and a sterile, transparent film that covers the top of the wound but does not touch it. An infrared warming card is inserted into a pocket in the film covering. Treatments are typically administered 3 times per day in 1-hour sessions.

MolecuLightDX™ and MolecuLight *i:X™* Fluorescence Imaging System (MolecuLight, Inc.) are handheld fluorescence imaging devices intended to assist wound debridement and treatment by allowing real-time visualization of bacterial contamination in the wound bed. In a darkened room or under a small drape, a clinician uses the device to illuminate the wound surface with 405 nm violet light. The device displays the fluorescent signal on its screen and calculates wound size and bacterial burden. Green fluorescence from skin components such as collagen and fibrin can provide anatomical context. Red and cyan fluorescence are associated with regions of bacterial loads. Red fluorescence detects Gram positive, Gram negative, aerobic and anaerobic bacterial species such as *Pseudomonas aeruginosa, Escherichia coli* (*E. coli*), *Staphylococcus aureus*, and *Clostridium perfringens*, as well as others. Fluorescence detection with the MolecuLight devices does not require contrast agents.

Regulatory Status

The Warm-up Wound Therapy® system (Augustine Medical, Inc.) received 510(k) approval from the U.S. Food and Drug Administration (FDA) in 1997 as a wound and burn occlusive heated dressing. (Product code: MSA). (1)

The FDA provided 510(k) clearance for the MolecuLightDX™ and the MolecuLight *i:X™* in 2021 based on review of predicate devices. Both devices are indicated for diagnosing and treating skin wounds, at the point of care, to 1) view and digitally record images of a wound; 2) measure and digitally record the size of a wound; and 3) view and digitally record images of fluorescence emitted from a wound when exposed to an excitation light. (Product code: QCR). (2, 3)

Rationale

This medical policy was created in 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was conducted through April 2024.

Standard components of wound care include sharp debridement of devitalized tissue, infection control, non-weight bearing, and treatment of underlying co-morbidities, such as adequate nutrition or glycemic control in diabetics. Therefore, validation of any adjunct to standard wound management requires a randomized controlled trial (RCT) to isolate the contribution of the intervention compared to underlying wound management.

Noncontact Normothermic Wound Therapy
A literature review identified a small, randomized crossover trial of warm-up active wound therapy involving 13 patients who were followed up for 2 weeks. (4) Compared to the control group, more patients in the treatment group improved (62.5% vs. 37.5%). However, the term "improvement" was not fully defined, and no statistical analysis was provided.

Santilli and colleagues reported a two-week trial of warm up active wound therapy in which 17 patients with 31 wounds served as their own control. (5) Almost half of these patients, all refractory to prior therapy, reported complete healing within 12 weeks after treatment. While studies of wound healing therapies frequently use patients as their own control, this trial design cannot isolate the contribution of the intervention. It is possible that the wound healing effect may be in part due to increased attentiveness to underlying wound care rather than to the warmup active wound therapy itself.

Finally, Cherry and Wilson reported on a case series of 5 patients who received a two-week trial of warm up active wound therapy. (6) Although 4 of the 5 patients reported complete healing at 6-14 weeks after treatment, a case series does not permit isolation of the contribution of the warmup therapy. In addition, both in this trial and in the previous trial reviewed (2), it should be noted that wound healing occurred several weeks after discontinuation of the warmup therapy, further confounding any evaluation of the therapy.

In January 2002, the Centers for Medicare and Medicaid Services (CMS) published a review of the available literature of noncontact normothermic wound therapy, specifically literature focusing on the warmup active wound therapy device. (7) CMS identified 8 articles that met their selection criteria, including 5 randomized studies (two of which were not yet published) and 3 case series. Data were separately analyzed for different types of wounds, i.e., pressure ulcers, venous stasis ulcers, diabetic/neuropathic ulcers, non-healing surgical incisions, and other types of chronic wounds. The CMS review identified methodologic flaws in all the trials in ensuring standard wound care in all patients, reporting outcomes, or reporting statistical or clinical significance of outcomes. The CMS assessment offered the following conclusion:

"In summary, the medical literature does not support a finding that noncontact normothermic wound therapy (NNWT) heals any wound type better than conventional treatment. While the submitted studies purport better healing, due to serious methodologic weaknesses, inadequate controls, and a variety of biases, the improved outcomes could also easily disappear in a properly controlled randomized trial. Furthermore, there is no reason why such a trial could not be readily performed. A trial that would best answer our coverage concerns would be one in which there was randomization to three arms: 1) experimental arm which would receive NNWT; 2) experimental arm which would receive NNWT, but with the heating element turned off; and 3) control arm, which would only receive conventional therapy. Conventional therapy should be standardized across all three arms as applicable."

Since the CMS decision, results from four small studies (ranging in size from 16–36 patients) were published that found increased wound healing time with use of noncontact normothermic wound therapy. (8-11) However, none of these studies was a controlled randomized, three-arm trial to isolate the effect of the intervention and address the trial design issues noted. (8, 10, 11) In addition, stratification of wound size, duration, and location are also necessary in trial design.

Alvarez et al. conducted a small (49 patients) open-label randomized trial with standard therapy controls. (12) The study found an improvement in wound healing with NNWT; at 12 weeks, 18% of NNWT wounds had complete healing compared to 9% in the control group. However, as the authors noted, the three hours per day of off-loading (application for one hour three times per day), may have improved patient compliance to off-loading instructions. A study in a larger patient population with the appropriate control groups, as described, is needed.

Yue et al. (2018) conducted a systematic review to assess the effects of local warming therapy (LWT) in treating chronic wounds. (13) The inclusion criteria included published or unpublished RCTs analyzing the effects of LWT in the treatment of chronic wounds (pressure ulcers, venous ulcers, arterial ulcers, and diabetic foot ulcers). Two review authors independently conducted study selection. No RCTs met the inclusion criteria for this review, rendering it impossible to undertake a meta-analysis or narrative description of studies. Reviewers concluded that the effects of LWT for treating chronic wounds are unclear on the basis that they were unable to identify any studies that met the inclusion criteria for this review; quality improvement for LWT trials is urgently needed.

Noncontact Real-time Fluorescence Wound Imaging

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*). (14) In a clinical trial, trained clinicians digitally measured and captured fluorescence images to assess for presence of moderate to heavy loads of bacteria in 50 wounds (36 diabetic foot ulcers [DFU]; 4 venous leg ulcers [VLU]; 3 arterial leg ulcers; and 7 others) of unknown infection status in 39 patients. The device showed 95% accuracy in wound measurements. Of 50 wound images, 36 (72%) were positive for red/pink blush or cyan fluorescence; 11% were positive in the wound bed, 86% in the periwound tissue, and 3% in both the wound bed and periwound tissues. The findings were consistent across wound type.

Sampling of wounds was found to under-report bacterial loads relative to fluorescence-guided curettage samples. The authors reported several limitations to the use of the device. Bacteria deeper than 1.5mm from the wound surface cannot be detected due to inherent limitations of optical imaging. It does not indicate which bacterial species are present nor does it provide bacterial antibiotic sensitivities. Microbiological culture is still required to obtain that information. Fluorescence imaging must be performed under dark conditions; and the device has an indicator light informing the clinician when sufficient darkness has been achieved.

A pilot study by Serena et al. (2019) (15) evaluated 19 wounds (17 venous leg ulcers; 2 diabetic foot ulcers) 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). CSS 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. Four out of the 19 wounds (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 single-center prospective observational study, Hurley et al. (2019) (16) swabbed 43 wounds from 33 patients. The authors wanted to establish the accuracy of the wound imaging device at detecting bacteria. The majority of the wounds assessed were on the lower limb (n=21); other wounds were located on the thigh, upper limb, sacrum, scalp, chest wall (n=2 each), natal cleft, and abdomen (n=1 each). 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.

In a prospective, multi-site, observational study, Hill and Woo (2020) (17) examined the use of incorporating real-time bacterial fluorescence imaging into the UPPER/LOWER checklists to

enhance identification of infection in wounds. They noted that the UPPER/LOWER infection checklists look for signs and symptoms of local/superficial infection (UPPER) and deep infection (LOWER) to help clinicians in identifying and distinguishing between these infection levels, facilitating appropriate treatment. The presence of 3 or more UPPER or LOWER criteria is indicative of infection. They evaluated 43 chronic wounds (1 wound per patient). Infection was identified in 27 wounds (62.8 %) according to the UPPER/LOWER checklist criteria; 3 wounds were positive for both UPPER and LOWER infection, 1 wound was positive for LOWER infection only, and 23 wounds were positive for UPPER infection only. Fluorescence images were taken to detect wounds with high bacterial loads (greater than 10^4 CFU/g), indicated by the presence of red or cyan fluorescence. Red or cyan fluorescence from bacteria was observed in 88% of wounds (n = 38); all wounds positive for UPPER/LOWER were also positive for bacterial fluorescence. In 18 (41.9 %) of the 43 wounds, fluorescence information added a 3rd check to the UPPER/LOWER threshold, turning a negative diagnosis into a positive diagnosis of infection. Bacterial load was detected in 22/27 wounds swabbed, 17 of which exhibited heavy growth; in all wounds with detectable bacterial load, fluorescence signal was observed (PPV = 100 %, NPV = 83%). Using microbiology as ground truth, inclusion of fluorescence information as an additional item in the checklists increased the sensitivity of the UPPER/LOWER checklist from 82 % to 95 %. The authors concluded that the findings of this study suggested that the UPPER/LOWER checklist and fluorescence imaging work in a complementary manner to identify wounds with high bacterial burden at the point of care.

The authors stated that this study had several drawbacks. Both clinicians performing the evaluations were experts and familiar with the mnemonics and fluorescence imaging. Validation of the content of the mnemonics is needed to determine reliability of results among non-experts. Microbiology culture analysis was not available for all study wounds; therefore, the diagnostic accuracy measures reported in this study described 27 of 43 study wounds. The fluorescence imaging device could detect bacteria in wounds up to a maximum depth of 1.5 mm and did not provide real-time information on the bacterial species present or non-bacterial components (i.e., fungi) that may be present; wound sampling was needed to obtain this information. However, the high PPV of fluorescence reported in this trial, and in other studies, indicated that sampling may not always be needed. The single visit nature of this observational study prevented follow-up visits in most cases to examine if the treatment selections based on checklist classification and fluorescence information were appropriate. As outcomes data were not available for all patients to validate treatment plan changes, additional studies examining the impact of fluorescence-guided treatment selection are needed. However, in patients that were followed over multiple visits (e.g., case 6), reduction of UPPER/LOWER symptoms and bacterial fluorescence was observed at follow-up. Moreover, these researchers stated that due to the nature of the patient population, there was a low proportion of true negative study wounds (i.e., wounds with bacterial loads less than 10^4 CFU/g); therefore, specificity and NPV results should be interpreted with caution.

Armstrong et al. (2023) (18) conducted a post-hoc multicenter clinical trial analysis of 138 diabetic foot ulcers (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 (10^4 –10^9 CFU/g). Quantitative tissue culture confirmed the total loads. Bacterial presence was confirmed in 131/138 ulcers. Of these, 93.9% had loads > 10^4 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 10^4 –10^9 (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 > 10^4 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.

In 2024, ECRI Institute published an updated clinical assessment on the MolecuLight *i:X* device. (19) Their evidence review included one randomized controlled trial, 6 diagnostic cohort studies (described in 8 publications), and 1 before-and-after study reporting on 3,662 patients. ECRI concluded that MolecuLight *i:X* appears to be safe and identifies potentially harmful bacterial loads in chronic wounds. However, available studies provide insufficient evidence to determine whether adding the device to the standard of care improves patient-oriented outcomes for patients with chronic wounds. The studies assessed too few patients or report to few events (statistically imprecise) to be conclusive.

Summary of Evidence

Noncontact Normothermic Wound Therapy

In summary, improved health outcomes have not been demonstrated with the use of a noncontact radiant heat bandage. Additional studies are needed to further evaluate the safety and efficacy of this treatment modality. The evidence is insufficient to determine the effects of the technology on health outcomes.

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*:X* device, 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.

Ongoing and Unpublished Clinical Trials

Ongoing and unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05873049	Use of Real-time Fluorescence Imaging in Diabetic Foot Ulcers: A New Strategy to Assess Residual Bacterial Colonization Before Application of Artificial Dermis or Split-thickness Skin Graft	210	Oct 2024
Unpublished			
NCT04163055	The F.L.I.G.H.T. (Fluorescence Image-Guided Healing Trial) for Diabetic Foot Ulcers: A Phase IV Trial	294	Dec 2022 (status unknown; last update as of Nov 2020)
NCT04541394	Effectiveness and Clinical Application of MolecuLight Bacterial Fluorescence Imaging in Wound Debridement	200	Nov 2022 (status unknown; last update as of Mar 2021)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0598T, 0599T
HCPCS Codes	A6000, E0231, E0232

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
08/15/2024	Document updated with literature review. The following change was made to Coverage: Added: Noncontact real-time fluorescence wound imaging (e.g., MolecuLight) for bacterial presence is considered experimental, investigational and/or unproven for all indications. References 1-3, 14-19 added; others revised. Title changed from Noncontact Normothermic Wound Therapy.
06/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. No new references added.
02/01/2022	Reviewed. No changes.
03/01/2021	Document updated with literature review. Coverage unchanged. No new references added.
10/15/2020	Reviewed. No changes.
01/01/2020	Document updated with literature review. Coverage unchanged. The following references were added/updated: 4 and 10.
06/01/2017	Reviewed. No changes.

07/01/2016	New medical document originating from medical policy DME101.044. The following change was made to Coverage: Added “or noncontact wound warming device” to the following coverage statement: Use of noncontact normothermic wound therapy or noncontact wound warming device, either as a primary intervention or as an adjunct to other wound therapies, is considered experimental, investigational and/or unproven. Title changed from Noncontact Wound Therapy.