Molina Clinical Policy
MolecuLight Wound Care Device: Policy No. 397

Last Approval: 4/13/2022
Next Review Due By: April 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

The MolecuLight i:X and DX Imaging Devices are handheld medical imaging devices designed for point-of-care use to detect elevated loads of bacteria in wounds based on known intrinsic fluorescence characteristics. The devices are comprised of a high-resolution color LCD display and touch-sensitive screen with integrated optical and microelectronic components. The MolecuLight i:X and DX use patented technology to enable real-time standard digital imaging and fluorescence imaging in wounds and surrounding healthy skin of patients. The fluorescence image, when used in combination with clinical signs and symptoms, is intended to increase the likelihood that clinicians can identify wounds containing bacterial loads $>10^4$ CFU per gram as compared to examination of clinical signs and symptoms alone. The devices are also capable of performing digital wound area measurement to allow for monitoring of wound progress. Proposed benefits of use include improved accuracy of sampling, more effective wound cleaning and debridement, and enhanced anti-microbial stewardship. The devices should not be used to rule-out the presence of bacteria in a wound and do not diagnose or treat skin wounds.

The Food and Drug Administration (FDA) initially granted a de Novo classification for MolecuLight i:X device (DEN180008) on February 16, 2018, followed by clearance for marketing (K191371) through the FDA Premarket Notification process on December 4, 2019. An updated clearance for marketing (K210882) was granted June 22, 2021 with an additional labeling statement. According to FDA labeling the device is indicated as a tool for clinicians to view and digitally record images of a wound, measure and digitally record the size of a wound, and view and digitally record images of fluorescence emitted from a wound when exposed to an excitation light (FDA, 2019). A newer model, the MolecuLightDX, received clearance for marketing (K211901) on July 21, 2021 for the same indications (FDA, 2021). According to the manufacturer website, the DX has new features including sticker-less measurement capability, electronic medical record (EMR) integration options, an Administrator workflow and system configuration capability, and a docking system (MolecuLight Inc, 2021).

COVERAGE POLICY

The MolecuLight i:X and MolecuLight DX devices **are considered experimental, investigational, and unproven** based on insufficient evidence in the peer reviewed literature to support their use in identification and management of wounds.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Overall, the evidence base for the MolecuLight device is of low methodological quality and consists of prospective multi or single center observational studies and case series. There are no randomized controlled trials, meta-analysis or systematic reviews in the peer reviewed medical literature at the current time. A summary of applicable studies is outlined below.

Le et al. (2021) performed a prospective multicenter controlled study (n=350) from 14 outpatient advanced wound care centers across the United States. Wounds underwent assessment for clinical signs and symptoms (CSS) followed by fluorescence imaging (FL). Biopsies were collected to confirm total bacterial load. Three hundred fifty patients completed the study (138 diabetic foot ulcers, 106 venous leg ulcers, 60 surgical sites, 22 pressure ulcers, and 24 others). Results: Around 287/350 wounds (82%) had bacterial loads >10(4) CFU/g, and CSS missed detection of 85% of these wounds. FL significantly increased detection of bacteria (>10(4) CFU/g) by fourfold, and this was consistent across wound types ($p < 0.001$). Specificity of CSS+FL remained comparably high to CSS ($p = 1.0$). FL information modified treatment plans (69% of wounds), influenced wound bed preparation (85%), and improved overall patient care (90%) as reported by study clinicians. Innovation: This novel noncontact, handheld FL device provides immediate, objective information on presence, location, and load of bacteria at point of care. The authors concluded that the use of FL facilitates adherence to clinical guidelines recommending prompt detection and removal of bacterial burden to reduce wound infection and facilitate healing. The study limitations included no randomization or comparison to alternative wound management techniques, prospective assessment, and study results included only a post-assessment survey to assess the impact of FL on treatment plan.

Chew et al. (2020) evaluated the use of MolecuLight i:X to identify infections in acute open wounds in hand trauma. Data were collected from patients (n=35) who attended the hand trauma unit over a 4 week period prior to having surgery. Wounds were inspected for clinical signs of infection and autofluorescence images were taken using the MolecuLight i:X device. Wound swabs were taken and results interpreted according to report by microbiologist. Autofluorescence images were interpreted by a clinician blinded to the microbiology results. 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 autofluorescence imaging and 2 (5.7%) of wound swab samples were positive for significant infection. Autofluorescence imaging correlated with clinical signs and wound swab results for 34 wounds (97.1%). In one case, the clinical assessment and autofluorescence imaging showed positive signs of infection but the wound swabs were negative. The authors concluded that autofluorescence imaging in acute open wounds may be useful to provide real-time confirmation of bacterial infection and therefore guide management. Limitations of this study include a single-centre study restricts the reliability of findings, small sample size, no randomization or comparison to alternative wound management techniques.

Hurley et al. (2019) conducted a single-center prospective observational study (n=33) in an outpatient plastic surgery wound care clinic. Patients had their wounds photographed under white and auto-fluorescent light with the imaging device. Auto-fluorescent images were compared with the microbiological swab results. RESULTS: A total of 33 patients and 43 swabs were included, of which 95.3% (n=41) were positive for bacteria growth. Staphylococcus aureus was the most common bacterial species identified. The imaging device had a sensitivity of 100% and specificity of 78% at identifying pathological bacteria presence in wounds on fluorescent light imaging. The positive predictive value (PPV) was 95.4%. The negative predictive value (NPV) was 100%. It demonstrated a sensitivity and specificity of 100% at detecting the presence of Pseudomonas spp. Authors concluded that he imaging device used could be a safe, effective, accurate and easy-to-use auto-fluorescent device to improve the assessment of wounds in the outpatient clinic setting. In conjunction with best clinical practice, the device can be used to guide clinicians use of antibiotics and specialized dressings. Limitations of this study include a single-centre study restricts the reliability of findings, small sample size, no randomization or comparison to alternative wound management techniques.

Raizmen et al. (2019) conducted a clinical trial of (n=50) wounds to assess the accuracy, clinical incorporation and documentation capabilities of a handheld bacterial fluorescence imaging device (MolecuLight i:X). Benchtop wound models with known dimensions and clinical wound images were repeatedly measured by trained clinicians to quantify accuracy and intra/inter-user coefficients of variation (COV) of the imaging device measurement software. Wound dimensions were digitally measured and fluorescence images were acquired to assess for the presence of bacteria at moderate-to-heavy loads. Fluorescence imaging was implemented into the routine assessment of 22 routine diabetic

foot ulcers (DFU) to determine appropriate debridement level and location based on bacterial fluorescence signals. According to the results, wound measurement accuracy was >95% (COV <3%). In the clinical trial of 50 wounds, 72% of study wounds demonstrated positive bacterial fluorescence signals. Levine sampling of wounds was found to under-report bacterial loads relative to fluorescence-guided curettage samples. Furthermore, fluorescence documentation of bacterial presence and location(s) resulted in more aggressive, fluorescence-targeted debridement in 17/20 DFUs after standard of care debridement failed to eliminate bacterial fluorescence in 100% of DFU debridements. The authors concluded that he bacterial fluorescence imaging device can be readily implemented for objective, evidenced-based wound assessment and documentation at the bedside. Bedside localization of regions with moderate-to-heavy bacterial loads facilitated improved sampling, debridement targeting and improved wound bed preparation. Limitations of this study include small sample size, no randomization or comparison to alternative wound management techniques.

Blumenthal et al. (2018) conducted a pilot study (n=20) using the MolecuLight i:X camera in the management of burns to demonstrate the ability of the device to guide clinicians in their management of the burn (ie, detect, identify, and specify swabbing locations). Burn wounds were photographed under standard light and violet light illumination to compare presentations of obvious infection signs and symptoms. Microbiology swab samples were obtained to correlate any bacterial presence to the images. The fluorescence images were used to guide swabs to where the bacteria were congregating. Twenty patients were imaged. 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. Nine of the patients, by definition, had infections. These findings were correlated with the typical signs and symptoms of infection, the fluorescence images, and the microbiology results. The efficacy of the MolecuLight i:X is evident due to the microbiology results correlating to the images. The authors concluded that further research is being done to test the device in terms of being an early intervention tool and that early results and guidance of swab samples indicate that 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. Limitations of this study include a single-centre study restricts the reliability of findings, there are no statistical analysis of results, small sample size, no randomization or comparison to alternative wound management techniques.

A MedTech Innovation Briefing published by the National Institute for Health and Care Excellence (NICE, 2020) states, "The current evidence is insufficient to support the MolecuLight i:X device when used for identification and management of wounds with bacterial burden or to prove safety and efficacy of the device as a tool for wound care management." Regarding the current published evidence, the publication notes that sample sizes are small and there are a limited range of outcomes. Additionally, there is a lack of evidence on wound closure times and the effect on antibiotic usage. Multicenter randomized controlled trials are needed to appropriately assess the efficacy and impact of this technology.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (e.g. lower extremity)
0599T	Each additional anatomic site (e.g. upper extremity); list separately in addition to code for primary procedure; use 0599T in conjunction with 0598T.

HCPCS Code

HCPCS	Description
E1399	Durable medical equipment, miscellaneous

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

04/13/2022 References and Summary of Evidence updated. No changes to coverage policy.
04/05/2021 New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS. Accessed February 15, 2022.
2. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of safety and effectiveness data: K191371, 510(k) summary. MolecuLight i:X. December 4, 2019. Available from FDA. Accessed February 15, 2022.
3. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of safety and effectiveness data: K210882, 510(k) summary. MolecuLight i:X. Available from FDA. Published June 22, 2021. Accessed February 15, 2022.
4. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of safety and effectiveness data: K211901, 510(k) summary. MolecuLight DX. Available from FDA. Published July 21, 2021. Accessed February 15, 2022.

Other Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on February 24, 2021 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of General Surgery. Additional references cited by the reviewer include Farhan et al. (2021), Farhan & Jeffery (2020), Piipe et al. (2019), Price (2020), Rennie et al. (2019), and Rennie et al. (2017).
2. MolecuLight Inc. Manufacturing [website]. https://us.moleculight.com/. Accessed February 15, 2022.
3. MolecuLight Inc. October 14, 2021. Launch of new MolecuLightDX™ device to enable point-of-care imaging of wounds in new expanding market segments [Press release]. Available from MolecuLight. Accessed February 15, 2022.

Peer Reviewed Publications

1. Blumenthal E, Jeffery SLA. The use of the moleculight i:X in managing burns: A pilot study. J Burn Care Res. 2018 Jan 1;39(1):154-161. doi: 10.1097/BCR.0000000000000565. Accessed February 15, 2022.
2. Chew BJW, Griffin M, et al. The use of moleculight i:X device in acute hand trauma. J Plast Reconstr Aesthet Surg. 2020 Jul;73(7):1357-1404. doi: 10.1016/j.bjps.2020.03.004. Accessed February 15, 2022.
3. Hurley CM, McClusky P, Sugrue RM, et al. Efficacy of a bacterial fluorescence imaging device in an outpatient wound care clinic: A pilot study. J Wound Care. 2019 Jul 2;28(7):438-443. doi: 10.12968/jowc.2019.28.7.438. Accessed February 15, 2022.
4. Le L, Baer M, Briggs P, Bullock N, et al. Diagnostic accuracy of point-of-care fluorescence imaging for the detection of bacterial burden in wounds: Results from the 350-patient fluorescence imaging assessment and guidance trial. Adv Wound Care (New Rochelle). 2021 Mar;10(3):123-136. doi: 10.1089/wound.2020.1272. Accessed February 15, 2022.
5. Raizman R, Dunham D, Lindvere-Teene L, et al. Use of a bacterial fluorescence imaging device: Wound measurement, bacterial detection and targeted debridement. J Wound Care. 2019 Dec 2;28(12):824-834. doi: 10.12968/jowc.2019.28.12.824. Accessed February 15, 2022.

National and Specialty Organizations

1. National Institute for Health and Care Excellence. MolecuLight i:X for wound imaging. Medtech Innovation Briefing. Available from NICE. Published June 18, 2020. Accessed February 15, 2022.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Andersen CA, McLeod K, Steffan R. Diagnosis and treatment of the invasive extension of bacteria (cellulitis) from chronic wounds utilising point-of-care fluorescence imaging. Int Wound J. 2021 Oct 5. doi: 10.1111/iwj.13696. Accessed February 15, 2022.
2. Blackshaw E, Jeffery S. Efficacy of an imaging device at identifying the presence of bacteria in wounds at a plastic surgery outpatient clinic. J Wound Care. 2018 Jan 2;27(1):20-26. doi: 10.12968/jowc.2018.27.1.20. Accessed February 15, 2022.
3. Cole W, Coe S. Use of a bacterial fluorescence imaging system to target wound debridement and accelerate healing: a pilot study. J Wound Care. 2020 Jul 1;29(Sup7):S44-S52. doi: 10.12968/jowc.2020.29.Sup7.S44. Accessed February 14, 2022.
4. Farhan N, Jeffery S. Diagnosing burn wounds infection: The practice gap and advances with MolecuLight bacterial imaging. Diagnostics (Basel). 2021 Feb 9;11(2):268. doi: 10.3390/diagnostics11020268. Accessed February 15, 2022.
5. Farhan N, Jeffery S. Utility of MolecuLight i:X for managing bacterial burden in pediatric burns. J Burn Care Res. 2020 Feb 19;41(2):328-338. doi: 10.1093/jbcr/irz167. Accessed February 15, 2022.
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12. Rennie MY, Lindvere-Teene L, et al. Point-of-care fluorescence imaging predicts the presence of pathogenic bacteria in wounds: A clinical study. J Wound Care. 2017 Aug 2;26(8):452-460. doi: 10.12968/jowc.2017.26.8.452. Accessed February 15, 2022.
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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*