Molina Clinical Policy
Autofluorescence Wound Imaging Device (MolecuLight and Multispectral Imager)
Policy No. 397

Last Approval: 02/11/2026
Next Review Due By: February 2027

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

Autofluorescent wound 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. These devices, such as the MolecuLight and Multispectral Imager, use patented technology to enable real-time standard digital imaging and fluorescence imaging in wounds and surrounding healthy skin of patients. The Multispectral Imager (MSI) allows clinicians to view and digitally record images of a wound, wound measurements, images of fluorescence emitted from a wound when exposed to an excitation light, and thermal images of a wound. The MSI has the additional capability to use an infrared sensor to capture a thermal image of the wound.

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. Proposed benefits of use include improved accuracy of sampling, more effective wound cleaning, and debridement, and enhanced antimicrobial 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.

Regulatory Status

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. According to FDA labeling, the device is indicated as a tool for clinicians to view and digitally record images of a wound, wound measurements, 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). On December 5, 2023, the FDA approved the Multispectral Imager Kit/ Multispectral Imager (MSI) (K230734) as substantially equivalent to the predicate devices with the same indications for use.

COVERAGE POLICY

Autofluorescence wound imaging devices (e.g., MolecuLight i:X, MolecuLight DX, and Multispectral Imager) 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.

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SUMMARY OF MEDICAL EVIDENCE

Overall, the evidence base for autofluorescent wound imaging devices is of low methodological quality and consists of prospective multi or single center observational studies, case series, and a randomized controlled trial. There are no meta-analyses, and until recently there were no systematic reviews in the peer-reviewed literature. The available evidence supports autofluorescence imaging as a potential adjunctive assessment tool; however, its use as a standalone diagnostic modality or as a determinant of treatment decisions is not supported by high-quality evidence.

Randomized Controlled Trials
A single-blinded randomized controlled trial by Rahma et al. (2022) examined the efficacy of bacterial autofluorescence imaging in treating diabetic foot ulcers (DFUs). Fifty-six DFUs were randomly assigned to receive either standard care with autofluorescence imaging (29 patients) or standard care alone (27 patients). The primary outcome assessed was the healing rate of ulcers at 12 weeks, with secondary measures including wound area reduction at 4 and 12 weeks, patient quality of life, and changes in management decisions post-autofluorescence imaging. The results showed a 45% healing rate at 12 weeks in the autofluorescence group compared to 22% in the control group. At 4 weeks, wound area reduction was 40.4% with autofluorescence imaging versus 38.6% without, and at 12 weeks, it was 91.3% with autofluorescence compared to 72.8% without. Secondary outcomes revealed a decline in quality of life among patients in the control group, while those in the autofluorescence-imaged arm experienced improvement. The study suggests that incorporating autofluorescence imaging alongside standard care may enhance DFU management.

Systematic Review and Meta-Analyses
Badrie et al. (2025) conducted a systematic review evaluating the diagnostic performance and clinical utility of autofluorescence imaging (AFI) for detecting clinically meaningful bacterial burden (≥10^4 CFU/g) in chronic and non-healing wounds. The review examined both diagnostic outcomes and functional clinical endpoints, including improvements in sampling accuracy, the precision of debridement, and changes in treatment planning. Across the 17 studies included, AFI consistently demonstrated higher sensitivity, specificity, and overall diagnostic accuracy than assessment using white light or clinical signs and symptoms alone, with several analyses showing statistically significant gains. Reported sensitivity values ranged broadly but reached as high as 100%, while specificity exceeded 90% in some cohorts; in multiple comparisons, AFI improved detection rates with p-values <0.05, including instances of more than a fourfold increase in identifying wounds above the bacterial load threshold ($p < 0.001$). AFI-guided sampling frequently revealed bacterial presence in areas that would have been missed by standard swabbing techniques, and fluorescence-directed curettage routinely produced higher bacterial yields than conventional methods ($p < 0.01$). Similarly, AFI-informed debridement was associated with significant reductions in surface bacterial fluorescence ($p < 0.001$) and more complete removal of contaminated tissue, and fluorescence-guided management often resulted in improved wound-area reduction compared to standard care (with differences reaching statistical significance at $p < 0.05$). Despite these promising findings, the evidence base displayed notable limitations, including heterogeneous study designs, variability in fluorescence interpretation and microbiological reference standards, device depth limitations (~1–1.5 mm), and a moderate degree of methodological bias; nearly half of the included studies did not meet predetermined validity thresholds. While statistically significant improvements in diagnostic accuracy and intermediate process measures were reported, the review emphasized that variability in study design, lack of standardized reference thresholds, and limited randomized evidence preclude conclusions regarding long-term clinical benefit.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence
Weigelt et al. (2022) published a summary to highlight the strengths and limitations of current imaging systems to help clinicians implement them and identify areas for future research. Advanced wound diagnostic tools can be difficult to use in clinical settings due to unclear benefits or incomplete validation. Various imaging modalities and devices can measure wound parameters like tissue oxygenation, burn depth, and bioburden. These technologies are advantageous due to their noninvasive nature and minimal risk to patients. Autofluorescence imaging is particularly promising for identifying bacterial loads that are not yet showing clinical signs and reducing false-negative results. Autofluorescence imaging is less effective with active bleeding, vascularized tissue, or silver dressings, as these can affect image interpretation. The blue light used penetrates only 1-1.5mm, limiting detection of deeper bacteria, and it cannot distinguish between commensal (microbes that live in and on the human body without causing harm) and pathogenic

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bacteria. Visualization depends on bacterial metabolic activity, meaning bacteria in biofilm may not be seen. Despite these limitations, AF imaging offers fast, simple, and effective feedback on bacterial bioburden and warrants further research in large clinical trials.

Wu et al. (2022) performed a prospective cohort study at a single center comparing the efficacy of Alcian blue staining to the MolecuLight i:X for biofilm detection in hard to heal wounds. A total of 53 participants were enrolled in the study. All study participants received wound evaluations and conservative sharp debridement by a plastic surgeon at their first outpatient clinic visit. Participants were then re-evaluated every 2 weeks for at least 90 days. Wound evaluations included an examination and recording of relevant wound characteristics to include microbiological wound culturing, modified wound blotting with Alcian blue staining protocol, wound bacterial fluorescence imaging (MolecuLight i:X), and standard wound imaging. Forty (75.5%) cases yielded positive wound culture results, 44 (83%) cases yielded positive wound blotting results, and 19 (35.8%) cases showed positive bacterial fluorescence. The detection mechanism of the MolecuLight i:X is based on detection of bacterial fluorescence within biofilm itself rather than the presence of biofilm. This creates the potential for false negatives when the biofilm has insufficient bacterial load for detection via fluorescence imaging. Additionally, the MolecuLight i:X must be held close to the target wound and the room must be dark, potentially posing a contamination risk compared to traditional wound culturing and wound blotting.

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). 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. 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 plans.

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. Three 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. 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 100% sensitivity and specificity at detecting the presence of Pseudomonas spp. Authors concluded that the 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

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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 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 debridement. The authors concluded that the 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 (e.g., 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.

National and Specialty Organizations

The **National Institute for Health and Care Excellence** (NICE 2020) published a MedTech Innovation Briefing stating, "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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
0598T	Real-time fluorescence wound imaging with clinical darkness, to identify location of bacterial wound pathogens and measure wound size, per session; first anatomic site (e.g., lower extremity, right leg)
0599T	Real-time fluorescence wound imaging with clinical darkness, to identify location of bacterial wound

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	pathogens and measure wound size, per session; each additional anatomic site (e.g., upper extremity, left leg) (List separately in addition to code for primary procedure)

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

02/11/2026	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
02/12/2025	Policy reviewed. No changes to coverage criteria. Policy name changed to Autofluorescence Wound Imaging Device (MolecuLight and Multispectral Imager). Updated Overview, Summary of Medical Evidence and References.
04/10/2024	Policy review, no changes to criteria. Updated Summary of Medical Evidence and References.
04/13/2023	Policy reviewed. References, Coding & Billing, and Summary of Evidence updated. No changes to coverage policy.
04/13/2022	References and Summary of Evidence updated. No changes to coverage policy.
04/05/2021	New policy.

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