Policy Title:	Policy – Non-Contact Wound Imaging for Bacterial Presence (MolecuLight ***i***/X®)	Number & Version:	UM-Wound Image MolecuLight
Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	1 of 4

I. POLICY STATEMENT and PURPOSE

The purpose of this policy is to describe the circumstances under which Non-Contact Wound Imaging for Bacterial Presence (MolecuLight ***i***/X®) would or would not be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

II. BACKGROUND

Fundamental to wound healing is the ability to identify and reducing harmful bacteria. Issues have been identified with the sensitivity of clinical examination and most wounds with elevated bacterial loads are undetected and incompletely treated (Le, 2021) (Rahma, 2022) (Serena, 2021). Elevated levels of bacteria impair wound healing rates (Lantis, 2013). Because of an increase in the aging population, increased incidence of diabetes, and other chronic disease states, the number and expense associated with chronic wounds continues to increase. Improved methods of detecting bacterial burden are being explored to improve patient outcomes and reduce the financial burden of infected wounds. A point-of-care fluorescence imaging device (MolecuLight i:X®) was developed to enable clinicians to noninvasively visualize the presence and location of bacterial loads (Oropallo, 2021).

III. SCOPE

This Policy applies to Non-Contact Wound Imaging for Bacterial Presence (MolecuLight ***i***/X®).

IV. DEFINITIONS

Chronic Wound: A chronic wound is described as one that has not progressed through an orderly and timely reparative process to create anatomic and functional integrity in time periods defined as little as four weeks and up to 3 months (Lazarus, 1994) (Werdin, 2009).

MolecuLight *i*/X®: A handheld imaging device intended for wound measurement and assessment developed to detect bacteria in wounds using a type of violet light to assist in making diagnostic and treatment decisions (Hayes, 2020).

Medically Necessary: Covered Services rendered by a Health Care Provider that the Plan determines are:

1) Safe and effective
2) Not experimental or investigational
3) Appropriate for patients,

a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
   i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,
   ii) furnished in a setting appropriate to the patient's medical needs and condition,
   iii) ordered and furnished by qualified personnel,
   iv) one that meets, but does not exceed, the patient's medical need; and
   v) is at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

The Director of Utilization Management is responsible for administration, oversight, and training regarding performance under this Policy.

VI. PROTOCOLS / COVERAGE POLICY

The use of Non-Contact Wound Imaging for Bacterial Presence (MolecuLight ***i***/X®) is not considered medically necessary for wound care management at this time. There is currently insufficient evidence to support its use in identification and management of wounds with bacterial burden. Studies in peer reviewed medical literature are limited. The evidence base for using MolecuLight i:X is lacking and sample sizes from existing studies are small. Outcomes are limited. There is also a lack of evidence related to any effects on antibiotic usage and wound closure timeframes.

VII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs)	None
CMS Local Coverage Determinations (LCDs)	None
CMS Articles	None

VIII. PROFESSIONAL REFERENCES / CITATIONS

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8. Werdin, F., Tennenhaus, M., Schaller, H. E., & Rennekampff, H. O. (2009). Evidence-based management strategies for treatment of chronic wounds. Eplasty, 9, e19. Accessed at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2691645/ on June 1, 2022.

IX. RELATED POLICIES / PROCEDURES

None

X. ATTACHMENTS

See Section VII.

APPROVALS:

	Printed Name	Signature
Senior Medical Director, UM:	Michael Fusco, MD	
Corporate Chief Medical Officer (QMMC Chair):	Debbie Zimmerman, MD	

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	06/01/2022	Gina Vehige	Original
02	04/19/2023	Gina Vehige	Original with Updated References; no change in coverage recommendation; FINAL Approved by MMC 6/30/2023; Effective 07/10/2023