

Policy Name:	Wound Imaging and Measuring Systems for Managing Chronic Wounds (e.g. Fluorescent Wound Imaging; Camera Wound Imaging)
Effective Date:	4/18/2022

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Wound imaging and measuring systems (e.g., fluorescent wound imaging; camera wound imaging) for managing chronic wounds are considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

Wound imaging systems are purported for use as noninvasive tools to monitor wound size in order to help inform decisions on wound management. These systems are suggested as faster, more accurate, and more reproducible alternatives to standard manual surface-area measuring. Some imaging systems can also determine wound depth, volume, and/or bacterial load.

MolecuLight i:X™ is an example of a handheld fluorescence imaging device intended to assist in wound debridement and treatment by allowing real-time visualizing of bacterial contamination in the wound bed. In a dark room a small drape is placed over the wound site and a clinician uses the MolecuLight device to illuminate the wound surface with ultraviolet light. The device displays the fluorescent signal on its screen and calculates wound size and bacterial burden.

Wound imaging systems using surgical cameras or portable electronics cameras (e.g., phones, tablets, custom devices) are used to record digital images and may include additional software for image analysis and data storage. Examples of camera-based devices include, but are not limited to, the Silhouette®, FastScan™, and Wound Tracker Professional systems.

FDA Approval

Wound imaging systems are subject to the FDA 510(k) Premarket Notification process, and are based on previous predicate device approval.

- The MolecuLight i:X fluorescence imaging device (MolecuLight, Inc.) was granted FDA marketing clearance in December 2019 (K191371) to aid in diagnosing and treating skin wounds at the point of care. The device is not intended to diagnose or treat skin wounds and is not to be used to rule-out the presence of bacteria in a wound.

Medica Coverage Policy



- The Silhouette system (Aranz Medical) is one example of a surgical camera and accessories for wound measurement and documentation. The system received FDA marketing clearance in 2007 for use on all external wound types to measure and document progression of external wounds over time.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- 0598T - Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)
- 0599T - Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)

Original Effective Date: 4/18/2022

Re-Review Date(s):

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