

# Code Compendium (Wound Care)



INDEPENDENT CARE HEALTH PLAN

Effective Date: 01/01/2024

Revision Date: Click or tap to enter a date.

Review Date: Click or tap to enter a date.

Policy Number: WI.PA-1051-000

Line of Business: Medicare

## Medicare Advantage Medical Coverage Policy

### Table of Contents

[Related Medical/Pharmacy Coverage Policies](#)

[Related Documents](#)

[Description](#)

[Coverage Determination](#)

[Coverage Limitations](#)

[Coding Information](#)

[References](#)

[Appendix](#)

[Change Summary](#)

#### Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

## Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

## Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Infrared Therapy Devices	<a href="#">270.6</a>		

LCD LCA	Wound Care	<a href="#">L37228</a>  <a href="#">A55909</a>	J5 - Wisconsin Physicians Service Insurance Corporation  J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE  IN, MI
LCA	Low frequency, non-contact, non-thermal ultrasound (CPT code 97610)	<a href="#">A56175</a>	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD LCA	Wound and Ulcer Care	<a href="#">L38902</a> <a href="#">A58565</a>	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Wound and Ulcer Care	<a href="#">L38904</a> <a href="#">A58567</a>	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Wound Care	<a href="#">L35125</a>  <a href="#">A53001</a>	JH - Novitas Solutions, Inc. (Part A/B MAC)  JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS  DE, D.C., MD, NJ, PA
LCA	Billing and Coding: Low Frequency, non-contact, non-thermal ultrasound	<a href="#">A54555</a>	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCD LCA	Near-Infrared Spectroscopy in Wound and Flap Management	<a href="#">L39385</a>  <a href="#">A59158</a>	JJ - Palmetto GBA (Part A/B MAC)  JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN  NC, SC, VA, WV
LCA	Billing and Coding: Low Frequency, non-contact, non-thermal ultrasound	<a href="#">A54555</a>	JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD LCA	Wound Care	<a href="#">L37166</a> <a href="#">A55818</a>	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

LCD LCA	Infrared Heating Pad Systems	<a href="#">L33825</a> <a href="#">A52477</a>	<p>DME A - Noridian Healthcare Solutions, LLC (DME MAC)</p> <p>DME B - CGS Administrators, LLC (DME MAC)</p> <p>DME C - CGS Administrators, LLC (DME MAC)</p> <p>DME D - Noridian Healthcare Solutions, LLC (DME MAC)</p>	<p>CT, DE, DC, ME, MD, MA, NH, NJ, NY, PA, RI, VT</p> <p>IL, IN, KY, MI, MN, OH, WI</p> <p>AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, PR, U.S. VI</p> <p>AK, AZ, CA, HI, ID, IA, KS, MO, MT, NE, NV, ND, OR, SD, UT, WA, WY, American Samoa, Guam, Northern Mariana Islands</p>
------------	------------------------------	--	---	--

## Description

This document houses assorted wound care CPT and HCPCS codes.

Provider Claim Codes	Section Title
97026, A4639, E0221	Monochromatic Infrared Energy Therapy
97610	Ultrasound Therapy for Wound Healing
0061U	Spatial Frequency Domain Imaging
0493T, 0640T, 0641T, 0642T	Near-Infrared Spectroscopy
0598T, 0599T	Noncontact Real-Time Bacterial Fluorescent Imaging of Wounds

**Monochromatic infrared energy (MIRE)** therapy involves the use of devices that deliver single wavelength nonvisible light energy from the red end of the light spectrum via flexible pads that are applied to the skin. Each pad contains 60 infrared emitting diodes. MIRE therapy is thought to stimulate the release of nitric oxide from the hemoglobin of the blood, which dilates the blood vessels, thereby reducing swelling and increasing circulation. MIRE has been proposed for treatment of conditions such as peripheral neuropathy, pain management and wound healing.

An example of a MIRE device includes, but may not be limited to, the Anodyne Therapy System.

**Low-frequency ultrasound** is proposed as an adjunct treatment to standard wound care. A noncontact, low-frequency ultrasound device is intended to promote wound healing through cleansing and debridement of the wound bed. The device is held 0.5 to 1.5 cm from the wound and saline is delivered to

the wound bed, which purportedly promotes healing through stimulation of cellular activity. Therapy generally consists of 3 to 12 minute sessions, three times per week.

Examples of low-frequency ultrasound devices include, but may not be limited to:

- AR1000 Ultrasonic Wound Therapy System
- AS1000 Ultrasound Wound Therapy System
- Jetox ND
- MIST Therapy System
- SonicOne O.R.
- SONOCA-185
- VERSAJET II Hydrosurgery System

Transcutaneous multispectral measurement of tissue oxygenation and hemoglobin using **Spatial Frequency Domain Imaging (SFDI)** is a noninvasive transcutaneous measurement of five biomarkers (tissue oxygenation [StO<sub>2</sub>], oxyhemoglobin [ctHbO<sub>2</sub>], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]) using SFDI and multi-spectral analysis. Examples of US Food & Drug Administration (FDA) approved devices include, but may not be limited to, the Clarifi Imaging System and the Ox-Imager CS.

**Near-infrared spectroscopy (NIRS)** is a noninvasive technique using wavelengths claimed to measure deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation in tissues within wounds as a proposed indication and potential of wound healing. An example of a US Food & Drug Administration (FDA) approved non-contact near-infrared spectroscopy device is the SnapshotNIR.

A handheld, **noncontact imaging tool** has been developed to aid clinicians in the assessment and treatment of chronic wounds during wound care. This device allows for viewing and digitally recording images, including the **fluorescence** emitted from the components of the wound (eg, bacteria, blood, skin, slough) when exposed to a violet light (excitation light). Those images would then purportedly detect the presence, location and load of clinically significant bacteria in order to inform decisions or revisions to an individual's treatment plan. An example of a US Food & Drug Administration (FDA) approved imaging device is the MolecuLight *i:X*.

## Coverage Determination

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:*

**Low-Frequency, Non-Contact, Non-Thermal Ultrasound (MIST Therapy)** will be considered medically reasonable and necessary when (all) the following requirements are met:

- Any of the following clinical conditions:
  - Wounds and ulcers which are too painful for sharp or excisional debridement and have failed conventional debridement with documentation supporting the same; **OR**
  - Wounds and ulcers meeting Medicare coverage for debridement but with documented contraindications to sharp or excisional debridement; **OR**
  - Wounds and ulcers meeting Medicare coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care
- Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) may be provided two to three times per week to be considered reasonable and necessary. The length of individual treatments will vary per wound size.
- Observable, documented improvements in the wound(s) should be evident after six treatments. Improvements include documented reduction in pain, necrotic tissue, or wound size, or improved granulation tissue.<sup>7-11</sup>

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following services/items will not be considered medically reasonable and necessary:

- Monochromatic Infrared Energy Therapy
- Spatial Frequency Domain Imaging
- Near-Infrared Spectroscopy
- Noncontact Real-Time Bacterial Fluorescent Imaging of Wounds

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

**Summary of Evidence*****Monochromatic Infrared Energy Therapy (MIRE)***

There is insufficient published evidence to assess the safety and/or impact of MIRE therapy on health outcomes or patient management for nonhealing wounds.<sup>26</sup>

There is insufficient published evidence to assess the safety and/or impact of MIRE therapy on patient management or health outcomes in patients with peripheral neuropathy.<sup>25</sup>

***Spatial Frequency Domain Imaging (SFDI)***

SFDI parameters measuring hemoglobin and oxygen-bound hemoglobin in the skin's dermis may eventually be used to estimate foot ulcer risk, but the available clinical research data are insufficient to determine how well it will work compared with other potential diagnostic methods. Additional studies are needed that compare SFDI with other imaging systems, such as optical coherence tomography, near-infrared spectroscopy, laser Doppler imaging, digital camera imaging, and thermal and fluorescence imaging.<sup>15</sup>

***Near-Infrared Spectroscopy (NIRS)***

The SnapshotNIR device detected normal spatial and temporal differences in tissue oxygenation over the operative course of alloplastic and autologous breast reconstruction. A multi-institutional, prospective clinical trial is needed to determine the sensitivity and specificity of this device for detecting skin flap necrosis.<sup>30</sup>

***Noncontact Real-Time Bacterial Fluorescent Imaging of Wounds***

Evidence from two diagnostic cohort studies and one before-and-after study suggests that adding MolecuLight i:X to CSS assessment improves identification of moderate-to-high bacterial loads in venous leg ulcers, pressure ulcers, and diabetic foot ulcers (DFUs), but the studies are at too high a risk of bias to determine whether MolecuLight i:X improves patient outcomes (e.g., complete wound healing, time to wound healing, infection rates).<sup>13</sup>

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
97026	Application of a modality to 1 or more areas; infrared	
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	

0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO <sub>2</sub> ], oxyhemoglobin [ctHbO <sub>2</sub> ], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis	
<b>CPT® Category III Code(s)</b>	<b>Description</b>	<b>Comments</b>
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)	
0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO <sub>2</sub> ]); image acquisition, interpretation and report, each flap or wound	
0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO <sub>2</sub> ]); image acquisition only, each flap or wound	
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO <sub>2</sub> ]); interpretation and report only, each flap or wound	
<b>HCPCS Code(s)</b>	<b>Description</b>	<b>Comments</b>
A4639	Replacement pad for infrared heating pad system, each	
E0221	Infrared heating pad system	

## References

1. American College of Physicians (ACP). Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians (ARCHIVED). <https://www.acponline.org>. Published March 3, 2015. Accessed August 14, 2023.
2. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Independent Diagnostic Testing Facility (IDTF) (A58559). <https://www.cms.gov>. Published January 1, 2023. Accessed August 31, 2023.

3. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Low frequency, non-contact, non-thermal ultrasound (A54555). <https://www.cms.gov>. Published October 1, 2015. Updated February 25, 2021. Accessed August 31, 2023.
4. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Low frequency, non-contact, non-thermal ultrasound (CPT code 97610) (A56175). <https://www.cms.gov>. Published November 1, 2018. Updated March 2, 2023. Accessed August 31, 2023.
5. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Infrared Heating Pad Systems (L33825). <https://www.cms.gov>. Published October 1, 2015. Updated January 1, 2020. Accessed August 31, 2023.
6. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Near-Infrared Spectroscopy in Wound and Flap Management (L39385). <https://www.cms.gov>. Published February 12, 2023. Accessed August 31, 2023.
7. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound and Ulcer Care (L38902). <https://www.cms.gov>. Published November 28, 2021. Accessed August 31, 2023.
8. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound and Ulcer Care (L38904). <https://www.cms.gov>. Published November 28, 2021. Accessed August 31, 2023.
9. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound Care (L35125). <https://www.cms.gov>. Published October 1, 2015. Updated July 23, 2020. Accessed August 31, 2023.
10. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound Care (L37166). <https://www.cms.gov>. Published December 7, 2017. Updated July 23, 2020. Accessed August 31, 2023.
11. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound Care (L37228). <https://www.cms.gov>. Published April 16, 2018. Updated April 27, 2023. Accessed August 31, 2023.
12. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Infrared therapy devices (270.6). <https://www.cms.gov>. Published October 24, 2006. Accessed August 14, 2023.
13. ECRI Institute. Clinical Evidence Assessment. MolecuLight i:X Fluorescence Imaging System (MolecuLight, Inc.) for managing chronic wounds. <https://www.ecri.org>. Published February 26, 2021. Accessed August 14, 2023.
14. ECRI Institute. Clinical Evidence Assessment. SonicOne O.R. system (Misonix, Inc.) for debriding wounds. <https://www.ecri.org>. Published October 6, 2017. Updated March 29, 2022. Accessed August 14, 2023.



15. ECRI Institute. Clinical Evidence Assessment. Spatial frequency domain imaging for assessing risk of foot ulcer development. <https://www.ecri.org>. Published November 11, 2022. Accessed August 14, 2023.
16. ECRI Institute. Clinical Evidence Assessment. Versajet hydrosurgery system (Smith & Nephew, Inc.) for debriding burn wounds. <https://www.ecri.org>. Published October 9, 2006. Updated April 21, 2022. Accessed August 14, 2023.
17. ECRI Institute. Clinical Evidence Assessment. Versajet II hydrosurgery system (Smith & Nephew, Inc.) for debriding chronic wounds. <https://www.ecri.org>. Published March 29, 2019. Updated April 11, 2022. Accessed August 14, 2023.
18. ECRI Institute. Hotline Response (ARCHIVED). Noncontact, low-frequency ultrasound for healing chronic wounds. <https://www.ecri.org>. Published November 21, 2007. Updated March 26, 2012. Accessed August 14, 2023.
19. ECRI Institute. Product Brief (ARCHIVED). MIST therapy system (Alliqua Biomedical, Inc.), noncontact, low-frequency ultrasound for healing chronic wounds. <https://www.ecri.org>. Published July 16, 2014. Updated December 2, 2016. Accessed August 14, 2023.
20. Hayes, Inc. Clinical Research Response. MolecuLight (MolecuLight Corp.). <https://evidence.hayesinc.com>. Published March 16, 2023. Accessed August 15, 2023.
21. Hayes, Inc. Health Technology Brief (ARCHIVED). Anodyne therapy system (Anodyne Therapy LLC) for peripheral neuropathy. <https://evidence.hayesinc.com>. Published February 25, 2008. Updated February 11, 2010. Accessed August 14, 2023.
22. Hayes, Inc. Health Technology Brief (ARCHIVED). Noncontact low-frequency ultrasound using the MIST therapy system (Celleration Inc.) for treatment of lower extremity arterial and diabetic foot ulcers. <https://evidence.hayesinc.com>. Published June 30, 2016. Updated June 8, 2018. Accessed August 14, 2023.
23. Hayes, Inc. Health Technology Brief (ARCHIVED). Noncontact low-frequency ultrasound using the MIST therapy system (Celleration Inc.) for treatment of venous leg ulcers. <https://evidence.hayesinc.com>. Published June 30, 2016. Updated June 8, 2018. Accessed August 14, 2023.
24. Hayes, Inc. Health Technology Brief (ARCHIVED). VersaJet II hydrosurgery system (Smith & Nephew Inc.) for treatment of burns. <https://evidence.hayesinc.com>. Published December 26, 2013. Updated December 9, 2015. Accessed August 14, 2023.
25. Hayes, Inc. Search & Summary (ARCHIVED). MIRE therapy (monochromatic infrared energy) for peripheral neuropathy. <https://evidence.hayesinc.com>. Published April 6, 2018. Accessed August 14, 2023.

26. Hayes, Inc. Search & Summary (ARCHIVED). MIRE therapy (monochromatic infrared energy) for treatment of wounds. <https://evidence.hayesinc.com>. Published April 6, 2018. Accessed August 14, 2023.
27. Landsman A. Visualization of wound healing progression with near infrared spectroscopy: a retrospective study. *Wounds*. 2020;32(10):265-271.
28. Lee S, Mey L, Szymanska AF, et al. SFDI biomarkers provide a quantitative ulcer risk metric and can be used to predict diabetic foot ulcer onset. *J Diabetes Complications*. 2020;34(9):107624.
29. MCG Health. Noncontact normothermic wound therapy. 27<sup>th</sup> edition. <https://www.mcg.com>. Accessed August 14, 2023.
30. Moritz WR, Daines J, Christensen JM, et al. Point-of-care tissue oxygenation assessment with SnapshotNIR for alloplastic and autologous breast reconstruction. *Plast Reconstr Surg Glob Open*. 2023;11(7):e5113.
31. National Pressure Ulcer Advisory Panel (NPUAP). Clinical Practice Guideline. Prevention and treatment of pressure ulcers/injuries: quick reference guide. <https://www.npuap.org>. Published 2019. Accessed August 14, 2023.
32. Neidrauer M, Zubkov L, Weingarten MS, Pourrezaei K, Papazoglou ES. Near infrared wound monitor helps clinical assessment of diabetic foot ulcers. *J Diabetes Sci Technol*. 2010;4(4):792-798.
33. Serena TE, Yaakov R, Serena L, Mayhugh T, Harrell K. Comparing near infrared spectroscopy and transcutaneous oxygen measurement in hard-to-heal wounds: a pilot study. *J Wound Care*. 2020;29(Sup6):S4-S9.
34. UpToDate, Inc. Basic principles of wound management. <https://www.uptodate.com>. Updated July 2023. Accessed August 14, 2023.
35. UpToDate, Inc. Clinical staging and management of pressure-induced skin and soft tissue injury. <https://www.uptodate.com>. Updated July 2023. Accessed August 14, 2023.
36. US Food & Drug Administration (FDA). 510(k) summary: Clarifi Imaging System. <https://www.fda.gov>. Published July 19, 2018. Accessed March 29, 2022.
37. US Food & Drug Administration (FDA). 510(k) summary: MolecuLight i:X. <https://www.fda.gov>. Published December 4, 2019. Accessed June 1, 2021.
38. US Food & Drug Administration (FDA). 510(k) summary: Ox-Imager CS. <https://www.fda.gov>. Published December 21, 2016. Accessed March 29, 2022.
39. US Food & Drug Administration (FDA). 510(k) summary: SnapshotNIR. <https://www.fda.gov>. Published November 10, 2020. Accessed August 24, 2022.

40. Weinkauff C, Mazhar A, Vaishnav K, et al. Near-instant noninvasive optical imaging of tissue perfusion for vascular assessment. *J Vasc Surg*. 2019;69(2):555–562.
41. Yafi A, Muakkassa FK, Pasupneti T, et al. Quantitative skin assessment using spatial frequency domain imaging (SFDI) in patients with or at high risk for pressure ulcers. *Lasers Surg Med*. 2017;49(9):827-834.

## Change Summary

- 01/01/2024 New Policy.