APWCA

AMERICAN PROFESSIONAL WOUND CARE ASSOCIATION

OFFICIAL POSITION STATEMENT

Point-of-Care Near-Infrared Spectroscopy Imaging in the Assessment and Management of Hard-to-Heal Wounds and Tissue Viability

Approved by the APWCA Board of Directors

November 12, 2026

Education / Advocacy / Collaboration

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The complete approved position statement follows, unchanged.

APWCA Position Statement: Point-of-Care Near-Infrared Spectroscopy Imaging in the Assessment and Management of Hard-to-Heal Wounds and Tissue Viability

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Sponsor: American Professional Wound Care Association (APWCA)

Approved by the APWCA Board of Directors: November 12, 2026

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1. Executive Summary

The American Professional Wound Care Association (APWCA) supports the reasonable and medically necessary use of point-of-care near-infrared spectroscopy (NIRS) imaging as an adjunct to comprehensive clinical assessment in the management of hard-to-heal wounds and in the assessment of tissue viability.

NIRS estimates tissue oxygen saturation (StO_2) and relative oxyhemoglobin and deoxyhemoglobin levels in superficial tissue at the wound and periwound. Conventional vascular tests provide complementary information. The ankle-brachial index (ABI), toe pressures, duplex ultrasound, and angiography assess pressure, flow, or vascular anatomy; they do not directly map superficial wound oxygenation. NIRS may add regional physiologic information that can be repeated at the point of care to assess change over time. A reassuring StO_2 value does not, by itself, establish adequate perfusion or the likelihood of healing. (1-4)

Observational studies and clinician consensus describe how NIRS information is used in routine practice. In a 22-state cohort of 19,192 wounds in 6,147 patients, clinicians used NIRS selectively in 4,060 wounds (21%). Imaging informed care plan evaluation, oxygenation trending, debridement, vascular referral, and plan of care classification. (1) This real-world experience is reinforced by recent multidisciplinary consensus regarding how NIRS is incorporated into clinical decision-making. An 18-member international Delphi panel reached consensus on 37 of 40 items (92.5%). The panel described NIRS as integrated across initial evaluation, procedural planning, treatment modification, referral, and longitudinal monitoring. (5)

The most developed outcome evidence concerns postoperative free flap monitoring, predominantly with attached sensors and nonrandomized comparisons. Systematic reviews report higher flap salvage rates with NIRS-assisted monitoring than with clinical monitoring alone. (6-8) Two blinded prospective cohorts support the predictive performance of noncontact intraoperative StO_2 assessment for skin flap necrosis. (9,10) These findings support the clinical utility of NIRS in flap monitoring, while additional evaluations may be needed to determine its degree of impact on healing outcomes in hard-to-heal wound management. In hard-to-heal wounds, a randomized trial of hyperbaric oxygen schedules in venous leg ulcers used serial NIRS as a measurement tool. StO_2 trends distinguished healing from nonhealing ulcers, while transcutaneous oxygen pressure ($TcPO_2$) did not. Patients were randomized to treatment schedules, not to NIRS-guided care. The trial therefore supports the prognostic value of serial StO_2, not improved outcomes from NIRS-guided management. (11) Further observational studies show physiologic response to revascularization and other therapies, and describe persistent oxygenation differences after visual closure. (12-16)

Key recommendations:

- APWCA supports the appropriate use of point-of-care NIRS imaging as an adjunct to clinical assessment when findings are reasonably expected to influence management. Coverage should apply when imaging is performed with an FDA-authorized device supported by device-specific performance evidence, and when medical necessity and the resulting management decisions are documented (Section 8). Blanket noncoverage would create a barrier to access that the available evidence does not justify.
- Use NIRS as an adjunct to, not a replacement for, history, physical examination, clinical judgment, and conventional vascular testing when indicated.
- Perform imaging, including repeat imaging, when the result is reasonably expected to influence management. Appropriate times include initial assessment of a hard-to-heal wound, stalled healing, discordant or nondiagnostic vascular testing, before and after revascularization or other interventions, before selected advanced therapies, and when determining wound resolution. For hard-to-heal wounds, imaging once weekly per wound reflects the usual cadence of wound reassessment. More frequent imaging is appropriate when medically necessary and documented, such as before and after a procedure or revascularization, or after an acute change in clinical status. This guideline describes typical use and should not be applied as a coverage limit when medical necessity is documented.
- Evaluate intraoperative tissue viability assessment and postoperative flap monitoring as distinct services, each under its own clinical criteria. Intraoperative assessment follows the procedure. Postoperative flap monitoring follows the surgical indication, institutional protocol, and clinical signs of compromise. Neither is subject to the weekly wound guideline.

2. Purpose and Target Audience

This statement summarizes the clinical rationale and published evidence for real-time point-of-care NIRS imaging. It sets out APWCA recommendations for clinical practice and for coverage policy. It addresses hard-to-heal wounds, surgical tissue viability, and postoperative flap monitoring, while distinguishing noncontact imaging from continuous contact-sensor monitoring.

It is directed to wound care providers, vascular and reconstructive surgeons, and to the Centers for Medicare & Medicaid Services (CMS), Medicare Administrative Contractors (MACs), Medicare Advantage Organizations, State Medicaid programs, commercial health plans, health technology assessment bodies, and medical policy and utilization management committees.

On October 1, 2026, five MACs posted parallel proposed local coverage determinations (LCDs) titled Near-Infrared Spectroscopy in Wound and Flap Management. Each would classify non-contact NIRS as noncovered for acute or chronic wound assessment and management and for intraoperative or postoperative flap assessment. The proposals are CGS Administrators (DL40466), National Government Services/Wellpoint Federal (DL40477), Noridian Healthcare Solutions (DL40458), Palmetto GBA (DL39385, a proposed revision of its existing noncoverage LCD L39385), and Wisconsin Physicians Service (DL40479). The stated

policy scope is noncontact NIRS; it should not be assumed to encompass every continuous contact-sensor service. This position statement reviews the evidence considered in those proposals, together with additional published evidence. (17)

Hard-to-heal wounds disproportionately affect older adults, Medicare beneficiaries, people with diabetes, and people with peripheral arterial disease (PAD). In these populations, unrecognized tissue hypoxia may contribute to delayed healing, infection, amputation, and hospitalization. (1-3,5)

3. Clinical Rationale: Regional Oxygenation and the Persistent Wound Environment

Oxygen is essential for cellular metabolism, collagen synthesis, angiogenesis, reepithelialization, and host defense against infection. A wound can have an adequate blood supply from a nearby major artery and still have reduced oxygenation in the tissue that must heal. Microvascular dysfunction and edema may impair local oxygen delivery, while inflammation and increased metabolic demand can alter the balance between oxygen delivery and use. (2,3)

Objective wound assessment is consistent with the theranostic framework described by Armstrong and colleagues in their review of tissue repair diagnostics. In this framework, timely measurements of wound biology, including inflammation and regional perfusion, complement clinical observation and inform treatment selection and reassessment. This is a rationale for measurement-informed care, not proof that a particular diagnostic device improves outcomes. (18)

Conventional vascular testing remains essential. Each test, however, addresses a specific question at a specific site (Table 1). ABI and toe indices measure pressure at the cuff site. Results must be extrapolated to a more distal wound. Medial arterial calcification, common in diabetes and end-stage renal disease, can falsely elevate or invalidate the ABI. Collateral flow can also be misleading. $TcPO_2$ measures oxygen tension at a single sensor site and is affected by edema, callus, cellulitis, and probe placement. The procedure itself is time- and labor-intensive. (2,3) In the Delphi consensus panel manuscript, access to conventional vascular testing varied by practice setting and geographic location. Although many clinicians reported that vascular testing was available within a 30-minute drive, providers in lower-access settings reported less consistent availability. Panelists identified delays in obtaining clinically actionable physiologic information as a potential contributor to adverse outcomes, including hospitalization and amputation, particularly in underserved settings. (5) These observations highlight the importance of timely access to physiologic information when managing patients with complex wounds.

Table 1. What conventional vascular tests and NIRS measure

Test	What it measures	Key limitation in hard-to-heal wounds
ABI / toe-brachial index	Systolic pressure ratio at the cuff site	Falsely elevated by medial calcification; does not assess the wound itself

Test	What it measures	Key limitation in hard-to-heal wounds
Duplex ultrasound	Flow velocity and anatomy of named arteries	Does not measure tissue oxygenation; operator dependent; access delays
Angiography	Arterial anatomy	Invasive; contrast exposure; defines anatomy, not tissue physiology
$TcPO_2$	Oxygen tension at one sensor site	Single point; affected by edema, callus, and placement; time intensive
NIRS imaging	Estimated StO_2 and relative oxyhemoglobin and deoxyhemoglobin levels across wound and periwound	Superficial depth; affected by pigmentation, edema, and wound bed material

Adapted from Arnold and Marmolejo (2) and Niezgoda et al. (3). StO_2, tissue oxygen saturation; $TcPO_2$, transcutaneous oxygen pressure.

NIRS and $TcPO_2$ are different measurements. StO_2 is the proportion of oxygenated hemoglobin in sampled tissue. $TcPO_2$ estimates oxygen partial pressure at a heated sensor. The two should not be treated as interchangeable. (3)

Interpretation of NIRS requires clinical context; a higher value is not always better. Interpretive reviews describe patterns that may accompany inflammation, local ischemia, and different phases of healing. These include increased periwound signal with reduced wound-bed signal, spatially heterogeneous signal, and changes during epithelialization and remodeling. Increased or persistent signal may reflect inflammation, infection, or hyperemia and is not specific for infection. Such patterns may help frame a clinical question and assess change over time, but they are not independently validated diagnostic criteria for infection, ischemia, or healing phase. They should be interpreted alongside the examination, wound trajectory, and conventional testing when indicated. (2)

Tissue oxygenation is one component of the wound environment. Armstrong, Edmonds, and Serena proposed the concept of chronic inhibitory bacterial load (CIBL) after a secondary analysis of a multicenter fluorescence-imaging study in diabetic foot ulcers. Their findings describe elevated bacterial burden that may extend beyond the visible wound bed despite few overt signs of infection. CIBL is a proposed clinical framework, not a stand-alone diagnosis of infection or an indication for systemic antibiotics. Bacterial fluorescence imaging assesses a different biological domain from NIRS tissue oximetry; neither should substitute for the other or for clinical assessment. (19)

4. The Technology and Device Eligibility

NIRS uses the differential absorption of near-infrared light by oxygenated and deoxygenated hemoglobin to calculate StO_2. Noncontact camera systems produce two-dimensional estimates of StO_2 and relative oxyhemoglobin and deoxyhemoglobin levels across the wound bed and adjacent skin. Image capture takes seconds and requires no direct contact with the patient or wound. The noncontact camera systems discussed here interrogate superficial tissue to a depth of approximately 2 to 3 mm; sampling depth is device dependent. (3,4) Other NIRS devices use attached sensors for continuous postoperative flap surveillance. (6,7) The cited noncontact NIRS imaging devices are cleared

by the US Food and Drug Administration (FDA) through 510(k) as Class II tissue saturation oximeters (21 CFR 870.2700, product code MUD). FDA-authorized labeling describes a noninvasive tissue oxygenation measurement system intended for use by healthcare professionals to assess oxygenation levels in superficial tissues. (4)

Independent academic groups, without manufacturer authorship or reported NIRS industry funding, have used noncontact NIRS imaging to measure known physiologic change. Investigators in Pisa mapped hand oxygenation during arterial occlusion and reperfusion in healthy volunteers and in patients with systemic sclerosis. (20,21) Investigators in Erlangen documented oxygenation changes with tourniquet ischemia and after negative pressure wound therapy (NPWT) (22,23) Investigators in Düsseldorf used NIRS to assess foot microcirculation after pseudoaneurysm treatment and during lipid-lowering therapy. (24,25) These studies show that the method responds to controlled changes in perfusion. They do not, by themselves, establish clinical benefit in wounds.

Devices differ in wavelengths, acquisition geometry, algorithms, calibration, and intended use. Performance with one platform should not be assumed for another. Wound imaging, intraoperative viability mapping, and continuous postoperative flap monitoring are different services. APWCA recommendations apply to a device only when both of the following are met:

- FDA marketing authorization with an indication for measuring tissue oxygenation in superficial tissue, or, for continuous flap monitoring, an indication for that use.
- Device-specific clinical performance data supporting the intended use, either published in the peer-reviewed literature or formally reviewed by FDA as part of the device's marketing authorization.

5. Methods

To inform this position statement, the author group conducted a structured narrative review of peer-reviewed literature on real-time point-of-care NIRS in wound care, tissue viability assessment, and flap monitoring available by November 11, 2026. The review examined physiologic measurement, vascular assessment, wound healing trajectory, treatment response, clinical decision-making, intraoperative viability, and postoperative flap outcomes. This was a structured narrative review, not a systematic review. It was not prospectively registered, and PRISMA reporting was not applied.

Literature searches covered PubMed, PubMed Central, ResearchGate, and publisher platforms. Regulatory and policy sources included the FDA 510(k) and product classification databases, AMA CPT resources, and the Medicare Coverage Database. Search concepts included "near-infrared spectroscopy," "tissue oxygen saturation," "wound," "ulcer," "flap," and "perfusion." Artificial intelligence-assisted search tools supplemented database searches, and all retrieved citations were verified against publisher or PubMed records.

Studies were evaluated by design, sample size, comparator, reference standard, statistical findings, and reported limitations. Attention was given to selection bias, confounding,

single-center designs, and whether outcomes demonstrated physiologic measurement, changes in clinical management, or improvements in patient outcomes. Overlapping primary cohorts across systematic reviews were identified to avoid treating them as independent evidence. Studies cited in the proposed LCDs were specifically cross-checked. (17)

Trade publications, conference posters, commercial white papers, and abstracts without peer-reviewed full text were excluded from the clinical evidence base. Manufacturer bibliographies were used only to locate primary sources. Editorials, educational frameworks, and consensus documents were cited for context and clinical framework, not as clinical evidence. Publications on wound theranostics, chronic inhibitory bacterial load, and fluorescence imaging-guided debridement were considered as context for complementary, measurement-informed care, not as evidence of NIRS efficacy. (18,19,26) Appendix A presents the principal NIRS studies, findings, and limitations.

Recommendations were informed by the totality of available evidence, with consideration of physiologic validity, clinical actionability, patient outcomes, safety, and the limitations of existing studies. Greater weight was placed on controlled and prospective evidence when evaluating clinical outcomes. Observational studies were considered supportive. FDA marketing authorization was not considered sufficient, by itself, to establish clinical benefit.

6. Evidence Summary

6.1 Real-world wound management and clinical decision-making

Kelso et al. evaluated 19,192 wounds in 6,147 patients treated in post-acute care across 22 states. NIRS was used in 2,165 patients (35%) and 4,060 wounds (21%). Clinicians imaged selectively, focusing on wounds with the greatest complexity or worsening status. Documented reasons included care plan evaluation (92.98%), StO_2 trending (66.65%), debridement assessment (29.16%), and microcirculation assessment or vascular referral (8.89%). After imaging, plans of care were updated to maintenance (20.76%), healable (17.39%), palliative (5.22%), or hospice (0.64%). Imaging also prompted additional studies (11.6%), vascular studies (10%), and vascular consultation or surgical referral (5.44%). Healing rates were 39.68% for all imaged wounds, 38.15% for lower extremity wounds, and 36.5% for pressure ulcers, compared with a previously published rate of 22.5% from the same practice and population. Because the comparison used historical rather than concurrent controls, the findings support the clinical utility of NIRS in informing management decisions but do not independently establish its effect on wound healing outcomes. (1)

The Delphi panel of 18 clinicians across podiatry, medicine, vascular and plastic surgery, nursing, and advanced practice reached consensus on 37 of 40 items, with very strong inter-rater agreement (median rWG, 0.92). Panelists reported that NIRS findings supported, and in some cases expedited, referral decisions (83.3%). The panel unanimously agreed that NIRS helps patients understand their plan of care by showing their response to treatment.

The three items that did not reach consensus concerned individual decision thresholds and prior authorization rather than the broader clinical utility of NIRS. (5)

6.2 Peripheral arterial disease and revascularization

In 43 patients with chronic limb-threatening ischemia, Schremmer et al. compared 27 patients who underwent endovascular treatment with 16 treated conservatively. After endovascular treatment, median wound StO_2 increased from 38% to 60% (P = .004), and wound area decreased from 343 to 178 mm^2 (P = .01). Neither changed significantly in the conservative group. Changes in wound StO_2, but not ABI, correlated with wound area reduction. (12) Geskin et al. examined 38 revascularized limbs in 30 patients. Tissue oxygenation changes after revascularization were not consistently correlated with ABI or acceleration time, suggesting that NIRS may provide information complementary to conventional tests. (13)

In 57 limbs in 34 patients, Reiter and Andersen found that the change in StO_2 during 60 seconds of 45° leg elevation was significantly greater in severe PAD (−17.2%) than in normal, mild, or moderate disease (P < .002 for all). Resting supine StO_2 did not differ (P = .23). The provocative maneuver, rather than a resting value, discriminated severe disease. (27) Niezgoda et al conducted a prospective study of 48 participants (91 limbs), the plantar-palmar StO_2 index rose with pulse-volume recording severity, from normal (1.054) through mild (1.178), moderate (1.376), and severe disease (1.430). It distinguished normal perfusion from all PAD categories (P < .005). (28) As a noncontact imaging modality that does not require arterial compression, NIRS offers a complementary approach to assessing regional tissue oxygenation, particularly when ABI measurements are limited by vascular calcification or noncompressible vessels. These preliminary findings support its potential role alongside conventional PAD testing. (3,28)

6.3 Wound healing trajectory, treatment response, and resolution

In a randomized controlled trial, Longobardi et al. assigned 81 patients with hard-to-heal venous leg ulcers to two hyperbaric oxygen schedules or conventional care. Seventy-three completed the study, and 511 NIRS images were analyzed. Healing wounds showed progressive changes in StO_2 at the wound center and edge. Nonhealing wounds did not. $TcPO_2$ did not correlate with healing. NIRS was the measurement tool rather than the randomized intervention, so the trial supports the prognostic value of serial StO_2 rather than testing NIRS-guided management. (11) In a retrospective study of 25 patients with diabetic foot or venous leg ulcers, Landsman described four patterns of wound and periwound oxygenation that appeared to distinguish wounds that went on to heal from those that did not. These patterns are descriptive and require prospective validation. (29)

NIRS also provides objective measurements of tissue oxygenation changes in response to adjunctive wound therapies. In 15 diabetic foot wounds treated with focused extracorporeal shock wave therapy, mean StO_2 increased 37.6% from baseline (P = .011), and wound area decreased significantly. (16) In 5 patients with recalcitrant wounds treated with continuous topical oxygen, StO_2 and wound area improved in all 5, and 3 healed within 5 weeks. (15) In 24 healthy volunteers, NIRS detected oxygenation changes across different

topical negative pressure levels. (30) In 21 healthy volunteers, the same group found increased oxygenation of the treated area after negative pressure was removed. (23) Interpretive reviews describe characteristic responses to compression, hyperbaric oxygen therapy, local anesthetic with epinephrine, and advanced tissue products. (2)

NIRS has also served as a secondary outcome measure in randomized trials of adjunctive therapy. In a double-blinded trial of home electrical stimulation in 33 patients with diabetic foot ulcers and PAD, wound area fell 22% at 4 weeks in the stimulation group and was unchanged in the control group. StO_2 showed no overall group effect but improved over time in stimulated patients with moderate to severe PAD. (31)

NIRS may provide additional objective information when assessing wound resolution. In 15 patients with 16 wounds, Andersen et al. found a mean 13.5-day interval (median 12 days; range 0 to 35 days) between visual reepithelialization and return of wound site oxygenation to that of surrounding intact skin. In one patient, rising StO_2 preceded recurrent breakdown and prompted resumption of offloading. These findings suggest that tissue oxygenation assessment may complement visual examination when evaluating wound resolution and determining the appropriate timing for transitioning from protective measures. (14)

NIRS has also guided tissue conservation. In a prospective cohort of 14 skin tear flaps in 11 patients, NIRS-identified viable flap tissue was preserved rather than excised. Median wound area fell from 9.1 cm^2 to 1.6 cm^2 ($P = .0001$). Median time to heal was 22 days, compared with 28 to 42 days in prior literature; this difference did not reach significance ($P = .82$). (32)

6.4 Intraoperative tissue viability

Two blinded prospective cohorts evaluated handheld NIRS during oncologic resection with flap reconstruction. In 42 patients (51 images), mean intraoperative StO_2 was 74.9% in control areas, 71.1% in at-risk areas, and 58.3% in areas that later necrosed. (9) In a 102-patient validation cohort, 18 patients (17.6%) developed skin flap necrosis. Low readings were a strong warning sign. Tissue with an StO_2 reading of 60% or lower usually went on to necrose (positive predictive value, 95%), and such readings were rarely seen in tissue that survived (specificity, 96%). High readings were reassuring. Readings of 85% or higher were rarely seen in tissue that later necrosed (sensitivity, 96%), and most such tissue survived (negative predictive value, 89%). A single cutoff of 72.5% correctly classified 86% of flaps that necrosed and 86% of flaps that survived. (10) Because surgeons were blinded to NIRS findings, these studies provide evidence of its predictive performance for tissue viability, while its impact on NIRS-guided operative decisions requires further evaluation. In 70 breasts undergoing alloplastic or autologous reconstruction, Moritz et al. documented expected spatial and temporal StO_2 patterns. No necrosis occurred, so accuracy could not be assessed. (33) Surgical series also describe intraoperative use. In mastectomy and flap reconstruction, surgeons have used noncontact NIRS to assess skin flap viability and guide debridement, particularly when the clinical examination is equivocal. (34,35)

6.5 Postoperative free flap monitoring

Postoperative free flap monitoring has the most developed clinical outcome evidence supporting NIRS. Most of this evidence comes from continuous monitoring with attached sensors rather than noncontact cameras. In a systematic review of 10 studies and 1,639 free flaps, Newton et al. reported salvage of 89% with NIRS-assisted monitoring versus 50% with clinical monitoring alone ($P < .05$). Partial flap loss after salvage was 16% versus 80%. (6) Kagaya and Miyamoto reported 99.1% sensitivity and 99.9% specificity for detection of vascular compromise when StO_2 was measured at least every 2 hours. (7) Chen et al. found significantly higher salvage and lower flap failure with NIRS monitoring. (8) Although these reviews include overlapping primary cohorts, heterogeneous monitoring devices, and predominantly nonrandomized studies, their findings consistently support the clinical value of NIRS in postoperative flap surveillance.

Table 2. Clinical applications of NIRS differ in purpose, technology, and evidence

Application	Clinical purpose	Device and timing	Principal evidence
Hard-to-heal wound assessment	Regional oxygenation, vascular referral, treatment response, and wound resolution	Noncontact camera; episodic, driven by a clinical question	Observational cohorts, prognostic data within randomized trials, and expert consensus (1,5,11-16,27-32)
Intraoperative tissue viability	Identify skin flap tissue at risk of necrosis	Noncontact camera; during surgery	Two blinded prospective cohorts and surgical series (9,10,33-35)
Postoperative free flap monitoring	Early detection of vascular compromise	Mostly attached sensors; continuous or frequent	Systematic reviews of predominantly nonrandomized studies reporting higher salvage (6-8)

Evidence for one application should not be assumed to transfer to another.

6.6 Evidence syntheses, consensus, and clinical frameworks

The multidisciplinary Delphi consensus manuscript addresses NIRS indications and workflow. Panelists reported use across pressure injuries (94.4%), crush injuries (94.4%), surgical dehiscence (83.3%), flaps (83.3%), and grafts (77.8%). Image acquisition was efficient. Interpretation, documentation, reporting, and care coordination accounted for most of the effort. (5)

The PRISM framework integrates perfusion imaging, regional bacterial status, infection staging, structural correction, and maintenance and monitoring into a single sequential pathway for hard-to-heal wounds. (3) Consensus statements and clinical frameworks provide guidance for integrating objective physiologic measurements into wound management, while additional outcomes research can further define their clinical and economic impact.

Fluorescence imaging-guided debridement provides a complementary example of linking an objective wound finding to a defined clinical action. Orkin and colleagues review the use of bacterial autofluorescence to localize bacterial burden and inform debridement. (26) By identifying different characteristics of the wound environment, bacterial fluorescence imaging and NIRS may provide complementary information to guide clinical assessment

and treatment decisions. NIRS assesses regional tissue oxygenation rather than bacterial burden. Together, these technologies illustrate the broader theranostic principle of using targeted measurements to inform treatment and monitor response. (18,19,26)

The proposed LCDs classify noncontact NIRS as noncovered for wound management and intraoperative or postoperative flap assessment. Their evidence summaries include flap systematic reviews and blinded cohorts, including the studies summarized above. **(6-10,17)** Although these summaries include evidence from continuous contact-sensor monitoring, the proposed noncoverage language specifically addresses noncontact NIRS, raising questions about the applicability of findings across different monitoring technologies and clinical applications. APWCA recommends that coverage determinations evaluate the clinical evidence, intended use, and medical necessity of each clinical application rather than applying a blanket noncoverage determination to all applicable clinical uses of noncontact NIRS. The Longobardi trial further supports the prognostic value of serial StO_2 measurements in assessing wound healing, although NIRS-guided treatment decisions were not independently evaluated. (11,17)

7. Clinical Practice Recommendations

1. Use NIRS imaging as an adjunct to clinical assessment in patients with hard-to-heal wounds when the result is expected to change management. Appropriate times include initial assessment, wounds failing to progress as expected, discordant or nondiagnostic vascular testing, before and after revascularization or other interventions, before cellular, acellular and matrix-like products (CAMPs) or grafting, and when determining wound resolution. (1,2,5,14)

2. Do not use NIRS as the sole basis to deny revascularization, declare a wound nonhealable, set an amputation level, or diagnose infection. In a threatened limb, do not delay urgent vascular evaluation to obtain NIRS. An abnormal regional value should prompt clinical correlation and, when indicated, formal vascular evaluation. (2,27)

3. Interpret StO_2 in context. Read the pattern across wound and periwound, not a single number. Consider phase of healing, edema, slough, eschar, tissue products in the wound bed, recent vasoconstrictors, and skin pigmentation. Trends over time are more informative than isolated values. Avoid fixed universal thresholds for debridement, revascularization, amputation level, or flap salvage. (2,36)

4. Use serial NIRS imaging, when clinically indicated, to assess tissue oxygenation changes associated with revascularization, compression, hyperbaric oxygen therapy, topical oxygen, and other adjunctive therapies. Interpret findings alongside the clinical course to inform decisions regarding treatment continuation or modification. (2,11,12,15,16)

5. Repeat imaging should have a documented clinical purpose, such as reassessing a wound that is not progressing, evaluating a meaningful change in clinical condition, or assessing response to an intervention. (5) For hard-to-heal wounds, once-weekly imaging per wound reflects the usual cadence of wound reassessment and is consistent with

APWCA's position on bacterial fluorescence imaging. More frequent imaging should be determined by medical necessity and documented, such as before and after a procedure or revascularization, or after an acute change in clinical status. This guideline should not be applied as a coverage limit when medical necessity is documented. Intraoperative assessment and continuous postoperative flap monitoring should follow the surgical indication and device labeling.

6. Imaging should be acquired and interpreted by personnel with demonstrated competency. Treatment decisions based on imaging should be made by appropriately licensed clinicians acting within their scope of practice. (2,5)

7. For intraoperative tissue viability assessment, use noncontact NIRS as an adjunct to clinical examination of skin flaps and margins. A low reading should prompt closer evaluation of the tissue rather than automatic excision. (9,10,34,35)

8. For postoperative free flap monitoring, use devices labeled for that purpose under an institutional monitoring protocol. Monitoring frequency and duration should follow the surgical indication. (6-8)

Table 3 summarizes how NIRS findings can inform specific management decisions.

Table 3. How NIRS findings can inform management

Clinical situation	NIRS finding	Management decision informed
Hard-to-heal lower extremity wound with reassuring, nondiagnostic, or unobtainable ABI	Reduced or heterogeneous wound and periwound oxygenation	Formal vascular evaluation or expedited vascular referral (1,2,5,12)
Wound stalled despite appropriate standard care	Persistently low or unchanged StO_2 over serial studies	Reassess offloading, compression, edema control, and candidacy for adjunctive therapy (2,11,15,16)
After revascularization or adjunctive therapy	Change in StO_2 from the prior study	Continue, modify, or escalate treatment (11,12,15,16)
Before CAMPs or grafting	Wound bed oxygenation and periwound pattern	Timing of application (2)
Debridement or tissue conservation	Viable versus poorly oxygenated tissue	Extent of debridement and preservation of viable tissue (32)
Visually closed wound	Persistent oxygenation difference from surrounding skin	Timing of step down from protective measures (14)
Surgical flap or mastectomy skin	Low intraoperative StO_2	Closer evaluation or debridement of at-risk tissue (9,10,34,35)

NIRS findings are interpreted with the examination and conventional testing. No single value mandates a specific intervention.

8. Appropriate Use and Documentation Framework

Responsible use links each imaging procedure to a defined clinical question and a documented decision. The framework below supports medical necessity review and discourages routine or unfocused imaging.

Appropriate clinical indications:

- Initial assessment of a hard-to-heal wound when regional oxygenation is uncertain and the result may change management.
- Wounds that fail to progress as expected despite appropriate standard care.
- Discordant, nondiagnostic, or unobtainable conventional vascular testing, including noncompressible vessels.
- Assessment before and after revascularization or other interventions expected to change tissue oxygenation.
- Assessment before CAMPs, grafting, or other advanced therapies.
- Assessment of wound resolution and timing of step down from protective measures.
- Intraoperative tissue viability assessment and postoperative flap monitoring, each under its own clinical criteria.

Documentation elements:

- The clinical question and why the result is expected to influence management.
- Relevant history and prior vascular testing, or why such testing is unavailable or unreliable.
- Device, anatomic regions imaged, and image quality, including confounders such as edema, slough, or pigmentation.
- Findings by location, including StO_2 values and pattern, compared with any prior study.
- Clinical interpretation integrated with the examination and wound trajectory.
- The resulting decision, such as vascular referral, change in therapy, procedural planning, or continuation of the plan with rationale.
- For repeat imaging, what has changed or what treatment response is being assessed.

Box 1 shows an illustrative documentation example.

Box 1. Illustrative documentation example (fictional patient)

Indication: Right plantar first metatarsal head ulcer present 8 weeks, with less than 40% area reduction over 4 weeks of offloading and standard care. ABI noncompressible. Clinical question: is regional oxygenation adequate to support healing, or is vascular referral indicated?
Technique: Noncontact NIRS with an FDA-cleared device. Regions imaged: wound bed, periwound, and plantar forefoot, with the contralateral forefoot for comparison. Callus debrided before imaging. Image quality adequate; no significant edema.
Findings: Reduced wound bed StO_2 with a mottled periwound pattern, lower than the contralateral forefoot.
Interpretation: Findings suggest regional hypoperfusion not reflected by the ABI.
Decision: Referred for formal vascular evaluation with toe pressures and arterial duplex. Advanced therapy deferred pending vascular results. Repeat NIRS planned after any revascularization to assess response.

Illustrative only. Not a required template for coverage.

9. Coverage and Policy Recommendations

The following are APWCA policy positions.

1. APWCA supports access to NIRS imaging as a point-of-care diagnostic service when performed with an eligible device (Section 4) and when the medical record documents how the findings informed management.

2. APWCA does not support blanket noncoverage of NIRS for wound and flap management. The limitations of the available studies do not justify noncoverage under every clinical circumstance, particularly when imaging guides a defined, medically necessary decision. (17)

3. Wound management, intraoperative tissue viability assessment, and postoperative flap monitoring should each be appraised on their own evidence. Although the proposed LCDs review flap studies, their overall rationale does not clearly distinguish the evidence supporting noncontact imaging from continuous contact-sensor monitoring or adequately address the clinical circumstances associated with each application. APWCA recommends application-specific coverage assessment that considers the relevant technology, clinical evidence, intended use, and medical necessity, including the comparative flap salvage findings and their limitations. (6-8,17)

4. Noncontact NIRS imaging is reported with Category III CPT codes 0640T (first anatomic site) and 0859T (each additional anatomic site). Effective January 1, 2024, code 0640T was **revised, and codes** 0859T and 0860T were introduced. Code 0860T separately describes noncontact NIRS screening for peripheral arterial disease (PAD). These codes describe noncontact imaging and should not be assumed to apply to continuous contact-sensor flap monitoring. (37) Coding and payment decisions are separate from coverage determinations, which Medicare Administrative Contractors (MACs) make under the reasonable and necessary standard. Coverage should be informed by the clinical evidence summarized in Section 6.

5. Coverage policy should provide a pathway for medically necessary use, with appropriate training and safeguards against unnecessary utilization. Documentation should follow the framework in Section 8, including the clinical question, findings by location, and the resulting management decision.

6. Coverage should give particular consideration to Medicare beneficiaries, residents of post-acute and long-term care facilities, and patients in areas with limited access to vascular laboratories. In these populations, timely access to point-of-care physiologic information may facilitate earlier clinical assessment, informed treatment decisions, and appropriate vascular referral, potentially reducing delays in care. (1,5)

10. Limitations

Of the technology:

- Noncontact NIRS imaging systems estimate superficial tissue oxygenation at a depth of approximately 2 to 3 mm, depending on the device. They do not directly measure arterial blood flow or define vascular anatomy. (3)

- Melanin absorbs near-infrared light. In 110 healthy volunteers, dorsal foot values differed in Fitzpatrick type VI skin, with some missing data; plantar values did not differ by skin type. Subsequent FDA 510(k) documentation reports improvements in measurement performance under varying tissue-scattering conditions in preclinical testing, reflecting continued technological refinement. (4,36) An independent study of breast radiation therapy describes a device feature that corrects StO_2 measurements for darker skin. (38) Independent validation of performance across skin tones in wounds remains a research priority.
- Edema, slough, eschar, coagulum, tissue products in the wound bed, ambient conditions, and motion can alter readings. Local vasoconstrictors and hyperbaric oxygen therapy change regional signal. (2)
- Increased signal does not always mean adequate perfusion. Inflammation, infection, and hyperemia can elevate StO_2. (2)
- Thresholds derived with one device and in one tissue type should not be applied to other platforms or flap types without validation. (9,10)

Of the evidence:

- No randomized trial has compared NIRS-guided management with usual care. The available randomized trials used NIRS as a measurement tool, so they support its prognostic value rather than demonstrating improved outcomes from NIRS-guided care. (11,31)
- The largest wound cohort compared healing with a historical benchmark rather than concurrent controls. (1)
- Most wound studies are small, single-center, and uncontrolled. Several were funded by the device manufacturer or include manufacturer-affiliated authors.
- Flap systematic reviews include overlapping primary cohorts, heterogeneous sensor devices, and predominantly nonrandomized comparisons. (6-8)
- Evidence directly evaluating the impact of NIRS-guided wound management on major clinical outcomes, including amputation and hospitalization, remains limited.
- Image interpretation requires training and improves with experience. (2)
- The Delphi consensus workflow analysis estimated 46 to 65 minutes of total encounter-related activities for the first wound or anatomic site, with an additional 14 to 20 minutes for each subsequent site. These estimates encompass patient preparation, image acquisition, interpretation, documentation, clinical decision-making, and care coordination. Because the estimates were based on clinician-reported workflow components rather than direct time-motion measurements, they should not be interpreted as the incremental time attributable solely to NIRS imaging. (5)

The APWCA supports prospective research and retrospective real-world evidence (RWE) to further define the effect of NIRS on healing, limb preservation, patient outcomes, and healthcare utilization.

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Appendix A. Principal Studies, Findings, and Limitations

Study	Design and population	Key findings	Limitations
Kelso 2025 (1)	Retrospective cohort; 19,192 wounds, 6,147 patients, 22 states	NIRS used selectively in 21% of wounds; informed care plans, debridement, and vascular referral	Historical benchmark; clinician selection
Kelso 2026 (5)	Modified Delphi; 18 panelists	37 of 40 items reached consensus; 46 to 65 min clinician effort for first site	Expert opinion; self-reported time; manufacturer supported
Longobardi 2020 (11)	RCT; 81 patients with venous leg ulcers	Serial StO_2 distinguished healing from nonhealing; $TcPO_2$ did not	NIRS not the randomized intervention

Study	Design and population	Key findings	Limitations
Schremmer 2024 (12)	Prospective; 43 patients with CLTI	Median wound StO_2 rose from about 38% to 60% **after angioplasty; no significant change with conservative care**	Single center; **nonrandomized comparison group**
Geskin 2022 (13)	Retrospective; 38 limbs	StO_2 change not consistently correlated with ABI	Small sample
Reiter 2024 (27)	Cross-sectional; 57 limbs	Elevation ΔStO_2 −17.2% in severe PAD ($P < .002$)	Resting StO_2 not discriminating
Niezgoda 2025 (28)	Prospective; 91 limbs	Plantar-palmar index distinguished normal from all PAD classes ($P < .005$)	Manufacturer funded; external validation needed
Andersen 2024 (14)	Prospective; 16 wounds	Oxygenation normalized a mean 13.5 days after visual closure	Small; no comparator
Cole 2021 (16)	Case series; 15 wounds	StO_2 rose 37.6% with shock wave therapy ($P = .011$)	No control
Cole 2024 (15)	Case series; 5 patients	StO_2 and area improved in all with topical oxygen	Very small; manufacturer authors
Reiter 2025 (32)	Prospective; 14 skin tear flaps	Area fell from 9.1 to 1.6 cm^2 with NIRS-guided conservation ($P = .0001$)	Small; historical comparison for healing time
Hill 2020 (9)	Blinded prospective; 42 patients	StO_2 58.3% in areas that necrosed vs 74.9% control	Single device and center
Hill 2024 (10)	Blinded prospective; 102 patients	StO_2 ≤60% 96% specific; 72.5% cutoff 86% sensitive and specific	Single device; mainly breast and melanoma
Newton 2020 (6)	Systematic review; 1,639 free flaps	Salvage 89% with NIRS vs 50% clinical monitoring	Overlapping, nonrandomized cohorts
Kagaya 2018 (7)	Systematic review; 15 clinical studies	99.1% sensitivity, 99.9% specificity for compromise	Heterogeneous devices
Suludere 2024 (36)	Prospective; 110 healthy volunteers	Dorsal differences in Fitzpatrick VI; plantar unaffected	Healthy subjects only
Landsman 2020 (29)	**Retrospective; 25 patients with DFU or VLU**	**Four oxygenation patterns associated with subsequent healing**	**Descriptive; single author; prospective validation needed**
Zulbaran-Rojas 2023 (31)	**Double-blinded RCT; 33 patients with DFU and PAD**	**No overall StO_2 group effect; time effect in moderate to severe PAD**	**NIRS a secondary outcome; small sample**