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APWCA
AMERICAN PROFESSIONAL WOUND CARE ASSOCIATION

POSITION STATEMENT

APWCA Position Statement: Point-of-care bacterial autofluorescence imaging in the assessment and management of hard-to-heal wounds

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Kernexus MED COMMS

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APWCA Position Statement: Point-of-care bacterial autofluorescence imaging in the assessment and management of hard-to-heal wounds

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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 bacterial fluorescence diagnostic imaging as an adjunct to comprehensive clinical assessment in the management of hard-to-heal wounds. This technology is also referred to as real-time fluorescence wound imaging (RTFWI), a term reflected in updated Current Procedural Terminology (CPT) coding and proposed Medicare coverage policies.

Most wounds exhibiting critical colonization or elevated bacterial burden, defined in this statement as bacterial loads above 10^4 CFU/g, do not exhibit clinical signs or symptoms that reliably indicate their presence within the wound bed. In a 350-patient multicenter trial, clinical assessment alone demonstrated a sensitivity of only 15.3% for detecting elevated bacterial bioburden. When bacterial fluorescence imaging was added, sensitivity increased to 61.0% while specificity was maintained.[1]
Fluorescence imaging provides actionable information at the point of care. In the largest studies, imaging findings altered treatment plans in approximately one-half to two-thirds of evaluated wounds, including changes in debridement, cleansing, tissue sampling, and antimicrobial management.[1,2] Two randomized controlled trials and multiple cohort studies further suggest that fluorescence-guided care may improve healing, reduce recurrent infection, and decrease unnecessary antimicrobial use.[3-7]

The evidence is strongest for improved detection of elevated bacterial burden and for its influence on treatment decisions. Evidence for downstream outcomes, including healing, infectious complications, and antimicrobial use, is growing and currently comes largely from single-center and observational studies.

Key recommendations:

- APWCA supports the appropriate use of point-of-care bacterial fluorescence diagnostic imaging as an adjunct to clinical assessment when findings are reasonably expected to influence wound management. Diagnostic imaging can reveal and localize elevated bacterial burden that is not apparent on clinical examination. These findings inform targeted debridement, microbiological sampling, antimicrobial management, and assessment of wound bed readiness before selected advanced therapies. Coverage should apply when imaging is performed with an FDA-authorized device supported by device-specific clinical performance evidence, and when medical necessity and the resulting management decisions are documented. Blanket noncoverage would create a barrier to access that the available evidence does not justify.
- Use bacterial fluorescence diagnostic imaging as an adjunct to, not a replacement for history, physical examination, clinical judgment, and microbiologic testing when indicated.
- Perform diagnostic imaging, including repeat diagnostic imaging, when the result is reasonably expected to influence management, including during initial wound assessment, when healing is stalled, before and after debridement, before selected advanced therapies, and when antimicrobial therapy is being considered. Diagnostic imaging should generally be no more than weekly unless more frequent imaging is medically necessary and documented.

2. Purpose and Target Audience

This statement summarizes the clinical rationale and published evidence for point-of-care bacterial fluorescence imaging. It sets out APWCA recommendations for clinical practice and for coverage policy. The statement addresses hard-to-heal wounds. Evidence from burns and surgical wounds is included where those wounds are at risk of delayed healing, such as before grafting, after dehiscence, or during perioperative care.

It is directed to wound care providers 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, all seven MACs issued proposed local coverage determinations (LCDs) that would classify real-time fluorescence wound imaging for bacterial presence as non-covered on the grounds that it is "not reasonable and necessary." The statutory public comment period closes November 14, 2026.[8] This statement reviews the evidence considered in those proposals, together with additional published evidence.

Hard-to-heal wounds disproportionately affect older adults, Medicare beneficiaries, people with diabetes, residents of skilled nursing and long-term care facilities, and people with impaired mobility.[9] In these populations, elevated bacterial burden and delayed recognition of infection may contribute to impaired healing, infectious complications, and increased antimicrobial use.[3,4,7,10,11]

3. Clinical Rationale: The Persistent Wound Environment

Hard-to-heal wounds commonly exist in a persistent pathological state. It is characterized by polymicrobial biofilm, dysregulated inflammation, and elevated bacterial burden that may be present before conventional clinical signs of

infection become apparent.[1,10-15] Standard clinical assessment and conventional culture techniques may therefore underestimate elevated bacterial burden.[1,14,15]

An independent systematic review of 15 studies (1,056 hard-to-heal wounds) found that the classic signs of infection, including purulent exudate, erythema, heat, and edema, had limited diagnostic value against deep tissue biopsy culture (likelihood ratio range, 0.8 to 2.3; Table 1). In a cohort of 64 wounds, the Infectious Diseases Society of America combination of signs did not discriminate infection against this reference standard (positive likelihood ratio, 0.96; negative likelihood ratio, 1.0), although confidence intervals were wide. This historical endpoint of at least

TABLE 1 | Clinical signs and swab culture against a historical quantitative tissue-culture reference standard in hard-to-heal wounds

Finding or test	Sensitivity	Specificity	Positive LR (95% CI)	Negative LR (95% CI)
Clinical signs and symptoms (Gardner 2009; 64 wounds, 39% infected)				
Purulent exudate	26%	65%	0.74 (0.29-1.5)	1.1 (0.86-1.6)
Erythema	32%	77%	1.4 (0.62-3.1)	0.88 (0.64-1.2)
Edema	20%	77%	0.87 (0.33-2.3)	1.0 (0.80-1.4)
Heat	12%	85%	0.80 (0.21-2.8)	1.0 (0.85-1.3)
Foul odor	20%	87%	1.5 (0.50-4.8)	0.92 (0.73-1.2)
IDSA combination of signs	52%	46%	0.96 (0.60-1.6)	1.0 (0.61-1.8)
Increasing pain	13%	99%	11 (0.58-200)	0.88 (0.75-1.0)
Quantitative swab culture (Gardner 2006; 83 wounds, 36% infected)				
Levine technique	57%	91%	6.3 (2.5-15)	0.47 (0.31-0.73)
Z-technique	63%	53%	1.3 (0.91-2.0)	0.69 (0.41-1.2)
Wound exudate	43%	75%	1.7 (0.95-3.3)	0.76 (0.53-1.1)

Adapted from Reddy et al.[16], Table 2. Selected quality level 1 and 2 studies. Infection was defined as at least 10^6 organisms per gram of tissue on deep tissue biopsy culture. A likelihood ratio (LR) near 1.0 means the finding does not change the probability of infection. Confidence intervals that include 1.0 indicate no significant diagnostic value. IDSA, Infectious Diseases Society of America; defined as purulent exudate or two or more signs of inflammation (pain, erythema, heat, or edema). CI, confidence interval.

10^6 organisms per gram differs from the approximately 10^4 CFU/g threshold used in fluorescence studies and from contemporary clinical diagnosis of infection. Increasing pain was the most useful single finding, but its absence did not rule out infection. Swab cultures added limited information unless the Levine technique was used.[16]

Bacterial fluorescence imaging provides clinicians with real-time, point-of-care information regarding the presence and location of elevated bacterial burden. Because bacterial burden is often unevenly distributed across the wound bed, identifying affected areas may facilitate targeted interventions, such as localized sharp debridement, while avoiding unnecessary treatment of unaffected tissue.[17,18] Published evidence demonstrates that fluorescence imaging can identify elevated bacterial burden in wounds that appear clinically uninfected by standard assessment.[1,19]

Elevated bacterial burden and biofilm are integral to the persistent wound environment and may stall progression through the normal healing cascade.[9-11,20-23]

In patients with diabetes, peripheral neuropathy, peripheral arterial disease, and immune dysfunction may diminish or mask the usual local manifestations of infection, complicating timely recognition.[24] Adjunctive information about the presence and location of elevated bacterial burden may therefore be particularly useful when examination findings are equivocal.

Elevated bacterial burden may be present in a stalled wound despite few conventional signs of infection, and it may extend beyond the visible wound bed. In a secondary analysis of a multicenter trial, fluorescence extended beyond the wound bed in 80 of 95 fluorescence-positive diabetic foot ulcers (84.2%). To describe this pathological state, clinical investigators established the concept of chronic inhibitory bacterial load (CIBL) as a clinical framework for elevated bacterial burden that may impede healing with or without clinical signs. It is not a threshold for infection.[25]

Fluorescence imaging can help localize this burden and inform targeted cleansing, debridement, and sampling. Reassessment after intervention can identify residual signal and guide the next step. This places imaging within wound bed preparation before advanced therapies, alongside adequate perfusion, pressure redistribution, and clinical assessment for infection.[26] A negative image alone does not establish sterility or wound bed readiness.

4. The Technology and Device Eligibility

Point-of-care bacterial fluorescence imaging detects bacterial autofluorescence. Violet excitation light illuminates the wound without contact. Many Gram-positive species, such as *Staphylococcus aureus*, and Gram-negative species produce porphyrins during heme biosynthesis. These porphyrins emit red fluorescence. *Pseudomonas aeruginosa* produces pyoverdine, a siderophore that emits cyan fluorescence. Healthy tissue, such as dermal collagen, emits green autofluorescence that provides anatomical contrast.[27,28] Published technical evaluations report that fluorescence is detectable at loads above approximately 10^4 CFU/g, to a tissue depth of about 1.5 mm, when ambient light is controlled.[27]

The US Food and Drug Administration (FDA) granted De Novo authorization for the first wound autofluorescence imaging device in 2018 (DEN180008, product code QCR). Devices with labeling for identifying wounds with bacterial loads above 10^4 CFU/g have since been cleared through 510(k) as Class II autofluorescence imaging adjunct tools for wounds (product code QJF). Authorized labeling states that fluorescence, combined with clinical signs and symptoms, increases the likelihood of identifying wounds with loads above 10^4 CFU/g. FDA labeling also states that the device should not be used to rule out the presence of bacteria.[29]

Most published clinical evidence was generated with a single device platform. Other FDA-authorized devices have clinical performance data, reviewed by FDA, that support the same cleared indication.[29] APWCA recommendations apply to a device only when both of the following are met:

- FDA marketing authorization with an indication for identifying wounds with bacterial loads above 10^4 CFU/g when used with clinical signs and symptoms.
- Device-specific clinical performance data supporting the cleared indication, 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 point-of-care bacterial fluorescence imaging published through October 6, 2026. The review examined diagnostic performance, bacterial localization, effects on clinical decision-making, antimicrobial stewardship, debridement, wound healing, infectious complications, and applications in surgical wound management.

Literature searches covered biomedical bibliographic databases, academic publisher platforms, and institutional repositories, including PubMed, PubMed Central, ResearchGate, MAG Online, MDPI, Wiley, SAGE, Oxford University Press, Frontiers, and university institutional repositories. Regulatory, consensus, and policy sources included FDA De Novo, 510(k), and product classification databases; AMA CPT Editorial Panel summaries; the Federal Register; the Medicare Coverage Database; Wounds International; and the National Institute for Health and Care Excellence (NICE). Search concepts included "fluorescence imaging," "autofluorescence," "bacterial burden," "wound," "ulcer," "burn," and "surgical site." Artificial intelligence-assisted search tools were used to supplement database searches, and all retrieved citations were verified against publisher or PubMed records.

Retrieved peer-reviewed clinical studies were considered according to their relevance to point-of-care bacterial fluorescence imaging and the outcomes addressed. Randomized controlled trials, prospective diagnostic studies, observational cohorts, and implementation studies were evaluated in the context of their design, sample size, comparator, reference standard, statistical findings, and reported limitations. Particular attention was given to potential selection bias, confounding, single-center designs, and whether reported outcomes demonstrated diagnostic performance, changes in clinical management, or improvements in patient outcomes. Secondary analyses of shared datasets, including the Fluorescence Imaging Assessment and Guidance (FLAAG) trial, were identified to avoid treating overlapping populations as independent evidence.

Studies reporting unfavorable or inconsistent findings were considered alongside those reporting favorable results. Studies cited in the proposed LCDs were specifically cross-checked.[8] Trade publications, conference proceedings, commercial white papers, and abstracts without peer-reviewed full text were excluded from the clinical evidence base. Editorials and consensus documents were cited for context and clinical framework, not as clinical evidence. Studies of devices without FDA marketing authorization, including experimental prototypes and consumer-grade devices, were not included.

Published clinical evidence was distinguished from device-specific performance data reviewed by the FDA. For other FDA-authorized devices with the relevant indication, publicly available regulatory performance findings were summarized separately and were not treated as equivalent to independently published evidence of clinical outcomes.

Appendix A presents the principal studies, findings, and limitations.

Recommendations were informed by the totality of available evidence, with consideration of diagnostic reliability, clinical actionability, patient outcomes, safety, and limitations of existing studies. Greater weight was placed on controlled and prospective evidence when evaluating clinical outcomes, while observational studies were considered supportive. Improved detection of elevated bacterial burden and changes in treatment decisions were distinguished from demonstrated improvements in healing or infectious complications.

Clinical and coverage recommendations reflect APWCA's interpretation of the available evidence in the context of appropriate wound management, FDA-authorized intended use, and medical necessity. Peer-reviewed publications establish the baseline for clinical benefit. FDA marketing authorization can establish that a device performs comparably for its cleared indication, but it was not considered sufficient, by itself, to establish clinical benefit. The recommendations recognize areas of stronger diagnostic evidence and more limited evidence for downstream clinical outcomes.

6. Evidence Summary

6.1 Detection of elevated bacterial burden

The pivotal FLAAG trial enrolled 350 patients at 14 US centers. Overall, 82% of wounds had elevated bacterial burden. Adding fluorescence imaging to clinical assessment raised diagnostic sensitivity from 15.3% to 61.0%, a fourfold gain. Diagnostic accuracy rose from 29.4% to 65.1%. Specificity (84.1%) was unchanged and positive predictive value was 94.6%. Treatment plans changed in 68.9% of wounds.[1]

Findings from most earlier and smaller studies are consistent with these results. A first-in-human study identified clinically significant bacteria missed by standard assessment, including in periwound tissue.[30] A prospective 60-wound study found a positive predictive value of 100% for elevated bacterial burden.[31] A 19-wound pilot found diagnostic sensitivity rose from 22% to 72%.[19] A post hoc FLAAG analysis of surgical wounds showed a 5.7-fold sensitivity gain.[32] In that surgical wound analysis, experienced readers achieved higher sensitivity than trial clinicians (77.3% vs 38.6%).[32] A skin tone analysis of the same trial found that clinicians reported erythema in 2.3% of wounds in patients with the darkest skin tones (Fitzpatrick V and VI) versus 13.4% in the lightest, despite comparable bacterial burden. Clinical sensitivity in this group was only 2.9%. Adding fluorescence imaging improved sensitivity 12-fold, the largest gain of any group.[33] Smaller single-center outpatient studies reported similar results.[34,35] Other small single-center studies reported lower accuracy, including in lower extremity diabetic wounds against tissue culture, at left ventricular assist device driveline exit sites, and in burns.[36-38] Several of these publications are secondary analyses of FLAAG rather than independent cohorts. The 19-wound pilot was registered under the same trial number as FLAAG, so some of its patients may also have been included in FLAAG.[1,19]

6.2 Localization, sampling, and biofilm

Fluorescence-guided sampling improved detection of clinically relevant bacteria compared with standard swab technique in lower extremity diabetic ulcers.[39] In a post hoc FLAAG analysis of 78 wounds biopsied at two sites, fluorescence-guided biopsy detected elevated bacterial burden in 98.7% of wounds versus 87.2% with standard sampling at the wound center (P=0.0059).[40] In a 40-wound study using a composite reference standard of electron microscopy and microbiology, fluorescence detected biofilm with 84% sensitivity but 27% specificity. Clinical signs had 45% sensitivity.[41] Fluorescence is therefore a marker of elevated bacterial burden, not a specific biofilm test.
A 2026 single-center study found that bacterial fluorescence intensity predicted 90-day healing and outperformed clinical signs of biofilm (area under the curve, 0.73 vs 0.53). Wound blotting for biofilm matrix also predicted healing (area under the curve, 0.92) but is not commercially available in the United States.[42] These findings suggest prognostic value in objectively assessing bacterial burden in the wound bed.

6.3 Treatment decisions and antimicrobial stewardship

In a real-world series of 990 analyzed wounds from 211 facilities, about 71% had elevated bacterial burden, but only 29.6% had clinical signs of infection. Imaging changed the treatment plan in 53.3% of wounds.[2] An inpatient implementation study at two hospitals found that imaging detected 70% more wounds with elevated bacterial burden than clinical assessment alone and changed treatment plans in 35% of cases. Before imaging, antimicrobials had been prescribed for 88% of wounds, although more than half were judged clinically negative for infection.[43] In FLAAG, antimicrobials were prescribed at similar rates whether clinical signs were present or absent (75.0% vs 72.8%).[44]
A prospective audit of 1,447 consecutive outpatient wound assessments at eight US centers excluded 9 wounds that had already healed, leaving 1,438 for analysis. It found that, among patients who received a prescription, systemic antibiotics were used in 8.2% with imaging versus 47.6% with standard care (P<0.0001). Prescribing of any kind was more frequent with imaging (87.3% with imaging vs 50.5% with standard care), but it was predominantly topical.[3] A UK pre/post analysis of 229 foot ulcers reported fewer patients receiving antibiotics (45% after adoption vs 67% before) and antimicrobial dressings (44% after vs 85% before), with lower dressing spend.[4] Smaller case series describe similar stewardship use.[45,46]

These findings support its potential role in stewardship, while not establishing that every reduction in prescribing represents improved care. Imaging may inform either escalation or reduction of treatment, depending on the complete clinical assessment. Fluorescence positivity alone does not establish infection or justify systemic antibiotics for a clinically uninfected diabetes-related foot ulcer. Absence of signal does not justify withholding treatment when clinical infection is present.[24]

6.4 Debridement

Imaging after standard debridement frequently shows residual fluorescence, prompting further targeted debridement.[17,18,47] In an 11-wound series, wound area increased while bacterial fluorescence persisted. Once targeted debridement eliminated the fluorescence, wound area decreased by a mean of 27.7% per week.[47]

A single-center randomized controlled trial of 200 patients compared surgical debridement guided by real-time fluorescence imaging with standard surgical debridement. With fluorescence guidance versus conventional debridement, residual bacterial area after debridement was 6.8% versus 30.0%, mean time to healing was 49.2 versus 63.0 days, and reinfection occurred in 4% versus 22% (all $P<0.001$). Hospital stay was 17.5 versus 21.5 days, and antibiotic duration was 15.5 versus 18.7 days, in the same order (both $P<0.01$).[5] The trial enrolled hospitalized patients, which may limit applicability to outpatient care.

Because imaging prompted additional debridement, the trial evaluated imaging-guided debridement as a strategy and cannot separate the effect of imaging from the extra debridement it informed.[5]

6.5 Healing and complications

Detection of elevated bacterial burden is an intermediate endpoint. Its clinical significance in wounds without clinical infection has not been established. For this reason, studies reporting healing, infection, and antimicrobial outcomes carry particular weight.

A pilot randomized controlled trial in 56 patients with diabetic foot ulcers reported 12-week healing of 45% with imaging versus 22% without. The trial was not powered for definitive efficacy conclusions.[6]

In 55 long-term care and skilled nursing facilities, 12-week healing of pressure injuries was 38.5% after imaging adoption versus 22.5% before ($P=0.007$). Infectious complications occurred in 4.2% after adoption versus 16.9% before ($P=0.007$). The adjusted hazard ratio for healing did not reach significance.[7] The UK foot ulcer analysis reported 12-week healing of 48% after adoption versus 39% before.[4] Wounds that converted from fluorescence-positive to negative showed greater area reduction than wounds that stayed positive.[48] Fluorescence also predicted delayed healing of dehisced perineal wounds.[49] In a prospective pilot of 10 patients receiving cellular, acellular and matrix-like products (CAMPs), 4 of 5 fluorescence-negative wounds achieved at least 40% area reduction at about 4 weeks, compared with none of 5 fluorescence-positive wounds ($P=0.048$).[50] These preliminary findings suggest a role for assessing wound bed readiness before advanced therapies.

6.6 Burns and grafting

In a single-center study of 38 burn patients, fluorescence before grafting predicted graft loss with 86% sensitivity and 98% specificity. Accuracy was calculated per square centimeter of grafted area, not per patient.[51] Pilot burn studies, including one in children, support feasibility and diagnostic value.[52,53] A recent scoping review concluded that adequately powered studies are still needed.[54]

6.7 Evidence syntheses and consensus

A 2025 systematic review of 17 studies found fluorescence imaging to be more accurate than white light imaging or assessment based on clinical signs and symptoms. It did not perform a meta-analysis or a formal Grading of Recommendations Assessment, Development and Evaluation (GRADE) certainty assessment.[55] A 2024 systematic review and meta-analysis of non-culture diagnostic methods included six fluorescence imaging studies. Fluorescence imaging combined with clinical signs and symptoms showed improved diagnostic accuracy, particularly in identifying elevated bacterial burden and guiding treatment changes. These data were synthesized narratively rather than pooled, and the authors advised cautious interpretation.[56] An international Delphi panel of 32 experts reached consensus on indications, including use in lower extremity diabetic ulcers and imaging when any one sign or symptom is present. The panel suggested imaging no more than weekly unless additional assessment is medically necessary, including before, during or after wound-care procedures.[57] A 2025 international consensus panel addressed surgical wounds. Eight surgeons and wound care specialists issued three statements. Imaging is recommended before surgery to identify elevated bacterial burden and guide planning, during surgery to direct debridement and confirm wound bed readiness before closure or grafting, and at early postoperative follow-up of 1 to 2 weeks to detect subclinical burden. The statements were developed at a single roundtable with an 80% agreement threshold, and the document was supported by a bacterial fluorescence imaging device manufacturer.[58] Consensus statements inform the practice framework. They do not establish clinical or economic benefit.

The proposed LCDs' discussion of IWII 2022 describes laboratory fluorescence microscopy using dyes, probes and tissue sections.[8,59](p. 17) Handheld bacterial autofluorescence imaging is a separate technique discussed elsewhere in that document.[59](pp. 44-45) The IWII 2026 update addresses the two techniques separately. It describes bacterial fluorescence imaging as an emerging point-of-care adjunct. It notes that locating bacterial fluorescence may help target therapeutic cleansing and debridement and select the most appropriate microbiological sampling site. It also states that the technique does not diagnose infection or identify biofilm specifically.[60](pp. 37-38) Coverage assessments should distinguish these techniques and consider the guidance relevant to handheld imaging.

External assessments have been more conservative. A 2020 NICE briefing characterized the then-available observational evidence as low quality. It predates the Rahma and Hsu randomized trials and the Kelso long-term care study.[61] A systematic review by Edwards and colleagues found insufficient-quality evidence to recommend the evaluated methods for diagnosing infection in hard-to-heal wounds in community settings.[62] Its assessment included two fluorescence-imaging studies and identified limitations in diagnostic performance and study design. However, the authors also recognized potential uses of fluorescence imaging in targeting treatment and debridement and in tracking wound healing. They discussed favorable findings from the Rahma pilot randomized trial and noted the need for a fully powered study. The review's conclusion about infection diagnosis should therefore be distinguished from the broader assessment of fluorescence-guided wound management.[62] Since the Edwards review, the 200-patient Hsu randomized trial has provided additional evidence of favorable clinical outcomes with fluorescence-guided debridement.[5]

7. Clinical Practice Recommendations

1. Use bacterial fluorescence diagnostic 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, before and after debridement, before cellular, acellular and matrix-like product (CAMP) or grafting procedures, during perioperative care of surgical wounds, and when systemic or topical antimicrobial therapy is being considered.[57,58]
2. Do not use a positive image alone to diagnose infection or to start antibiotics in a clinically uninfected wound. A negative image should be interpreted within the complete clinical assessment and should not, by itself, exclude wound infection. Imaging findings may inform antimicrobial decisions alongside the examination, patient risk factors, and other diagnostic information. When infection is clinically suspected, a negative image should not delay appropriate investigation or treatment. Obtain microbiologic specimens when indicated.[24,29]
3. Use fluorescence findings to target debridement, cleansing, and tissue sampling. Reimage after debridement when residual burden would change the plan. Complete elimination of signal is not required when tissue viability, perfusion, or anatomy argues against further debridement.
4. Incorporate imaging into antimicrobial stewardship programs to support both escalation and avoidance of antimicrobials.
5. Repeat diagnostic imaging should have a documented clinical purpose, such as reassessing a wound that is not progressing, evaluating a meaningful change in clinical condition, or guiding and assessing debridement. Diagnostic imaging generally should not exceed once weekly per wound. More frequent diagnostic imaging should be guided by medical necessity and appropriately documented, such as before and after debridement or after a change in clinical condition.[57]
6. Diagnostic 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.[32]

8. Coverage and Policy Recommendations

The following are APWCA policy positions.

1. APWCA supports access to bacterial fluorescence 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. The proposed LCDs acknowledge randomized and observational evidence reporting favorable healing and other clinical outcomes.[8] The limitations of those studies do not justify noncoverage under every clinical circumstance, particularly when imaging is used to guide a defined, medically necessary wound-management decision. Published clinical findings should be considered applicable to other FDA-authorized devices only after assessing their intended use, technological characteristics, and supporting clinical and performance evidence.
3. The service is reported with Category III CPT codes 0598T and 0599T through 2026. The AMA CPT Editorial Panel has accepted a Category I code for real-time fluorescence wound imaging, effective January 2027, with deletion of 0598T and 0599T.[63] CMS has proposed national valuation of this code in the CY 2027 Physician Fee Schedule.[64] Coding and payment decisions are separate from coverage determinations, which MACs make under the reasonable and necessary standard. Coverage should rest on the clinical evidence summarized in Section 6.
4. APWCA does not support blanket noncoverage of bacterial fluorescence imaging, which would create unjustified barriers to evidence-based care.[8] Coverage policy should provide a pathway for medically necessary use, with appropriate training and safeguards against unnecessary utilization. Documentation should include the clinical indication, image findings by location, and the resulting management decision, such as targeted debridement,

sampling, a change in antimicrobial therapy, or a decision to withhold antimicrobials.

5. Coverage should give particular consideration to Medicare beneficiaries and residents of long-term care and skilled nursing facilities. In these populations, fluorescence-guided care has been associated with higher unadjusted healing rates and fewer infectious complications.[7] Particular consideration should also be given to patients with darker skin tones, in whom clinical signs of infection are least reliable.[33]

9. Limitations

Of the technology:

- Not all organisms fluoresce. Some *Streptococcus* and *Enterococcus* species and most yeasts are not detected.[28]
- Detection is limited to loads above approximately 10^4 CFU/g and to superficial tissue of about 1.5 mm.[27]
- Ambient light, blood, silver and iodine dressings, some topical agents, tattoo ink, bone, tendon, and slough can mask or mimic signal.[27]
- Imaging does not distinguish colonization from infection and does not diagnose osteomyelitis or deep infection.
- Tunnels, sinus tracts, and deep undermining cannot be fully imaged with a handheld device.

Of the evidence:

- Both randomized trials were single-center. One was a pilot not powered for efficacy.
- Several publications are secondary analyses of the FLAAG trial rather than independent cohorts.
- In FLAAG, biopsy sites were guided by imaging when fluorescence was present, which may favor imaging (incorporation bias).
- Clinicians were not blinded in either randomized trial. The Hsu trial blinded patients only. The Rahma trial used blinded assessment of the primary outcome.[5,6]
- Changes in management were reported by unblinded clinicians, which may introduce bias.
- Few studies report amputation or hospital admission outcomes.
- Image interpretation improves with experience. In one analysis, experienced readers achieved about twice the sensitivity of trial clinicians.[32]
- Positive predictive values reflect the high prevalence of elevated bacterial burden in study populations, 82% in FLAAG, and will be lower where prevalence is lower.[1]
- The clinical significance of elevated bacterial burden in wounds without clinical infection has not been established.
- Outcome and resource-use data come mainly from observational and pre/post designs.
- No formal cost-effectiveness or budget impact analysis has been published.

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The authors used Claude (Anthropic), Perplexity, and ChatGPT (OpenAI) to assist with literature searches, table preparation, and grammar review. The authors reviewed and verified all content, including each citation against the source, and take full responsibility for the statement.

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Appendix A. Summary of Key Clinical Studies

The table summarizes the principal clinical studies cited in Section 6, including studies with unfavorable findings cited in the proposed LCDs. Clinical performance data reviewed by FDA for other authorized devices are listed separately because they have not been published in the peer-reviewed literature.

Study	Design and setting	Sample	Comparator or reference	Principal findings	Key limitations
A. Detection of elevated bacterial burden					
Le 2021, FLAAG[1]	Prospective diagnostic accuracy trial; 14 US centers	350 patients	Clinical assessment alone; tissue biopsy culture	Sensitivity 15.3% to 61.0% with imaging; specificity 84.1%; PPV 94.6%; plans changed in 68.9%	Biopsy site guided by imaging
Rennie 2017[31]	Prospective, single-blind	60 wounds	Quantitative culture	PPV 100% for elevated bacterial burden	Sensitivity and specificity not established
Serena 2019[19]	Single-center pilot	19 wounds	Clinical assessment alone; tissue culture	Sensitivity 22% to 72% with imaging	Small pilot; shares FLAAG trial registration
Hurley 2019[34]	Prospective outpatient pilot	33 patients; 43 swabs	Swab culture	Sensitivity 100%; PPV 95.4%	Few culture-negative samples; specificity not interpretable
Armstrong 2023[25]	Post hoc analysis of FLAAG	95 fluorescence-positive diabetic foot ulcers	Tissue biopsy culture	Fluorescence beyond the wound bed in 80 of 95 (84.2%)	Post hoc analysis
Sandy-Hodgetts 2022[32]	Post hoc analysis of FLAAG	58 surgical wounds	Clinical assessment alone; tissue biopsy culture	Sensitivity 6.8% to 38.6% with imaging (5.7-fold); 77.3% among experienced readers	Post hoc analysis; small subgroup
Johnson 2024[33]	Post hoc analysis of FLAAG by skin tone	FLAAG cohort	Clinical assessment alone; tissue biopsy culture	Clinical sensitivity 2.9% in Fitzpatrick V and VI; 12-fold gain with imaging	Post hoc analysis
Serena 2023[40]	Post hoc analysis of FLAAG; paired biopsies	78 wounds	Standard biopsy at wound center	Elevated bacterial burden detected in 98.7% with fluorescence-guided biopsy vs 87.2% with standard biopsy (P=0.0059)	Post hoc analysis
Koo 2023[36]	Prospective single-center pilot; diabetic foot wounds	35 patients; 48 wounds	Tissue culture	Sensitivity 64.1%; specificity 55.6%; PPV 86.2%; NPV 26.3%	Small single-center pilot
Olbrich 2025[37]	Prospective single-center; LVAD driveline sites	46 patients; 107 examinations	Swab culture	Sensitivity 13.5%; specificity 72.7%; PPV 52.6%; NPV 27.3%	Driveline exit sites, not hard-to-heal wounds; swab reference
Pijpe 2019[38]	Pilot; burn wounds	14 patients; 20 wounds	Swab culture	Sensitivity 78%; specificity 64%; PPV 64%; NPV 78%	Small pilot; swab reference
B. Biofilm					
Mayer 2024[41]	Prospective	40 wounds	Composite of electron microscopy and microbiology	Biofilm sensitivity 84%, specificity 27%; clinical signs sensitivity 45%	Small sample; low specificity for biofilm

Study	Design and setting	Sample	Comparator or reference	Principal findings	Key limitations
Wu 2026[42]	Retrospective single-center cohort	103 wounds	Wound blotting; clinical signs of biofilm	90-day healing AUC 0.73 for fluorescence vs 0.53 for clinical signs and 0.92 for blotting	Retrospective; single center; blotting not commercially available in the US
C. Treatment decisions and antimicrobial use					
Jacob 2023[2]	Retrospective real-world series; 211 facilities	990 wounds analyzed (1,000 enrolled)	Clinical signs	Elevated bacterial burden in about 71%, clinical signs in 29.6%; plans changed in 53.3%	No culture confirmation; no outcomes
DasGupta 2022[43]	Prospective inpatient implementation; 2 hospitals	26 wounds in 21 patients	Clinical assessment alone	70% more wounds with elevated bacterial burden detected with imaging than with clinical assessment; plans changed in 35%	Small sample; no statistical testing or microbiologic confirmation; no outcomes
Trafelet 2024[3]	Prospective audit; 8 US centers	1,438 wounds analyzed (964 standard care, 474 imaging); 1,447 assessed, 9 healed wounds excluded	Standard care	Among patients prescribed treatment, systemic antibiotics 8.2% with imaging vs 47.6% with standard care (P<0.0001); any prescription 87.3% with imaging vs 50.5%, mostly topical	Single first-visit snapshot; no outcomes; no wound severity adjustment
Price 2020[4]	Retrospective pre/post; UK	229 lower extremity wounds (101 before, 128 after); single clinic	Before adoption	After vs before adoption: antibiotics 45% vs 67%; antimicrobial dressings 44% vs 85%; 12-week healing 48% vs 39%	Observational pre/post design; no statistical testing
D. Debridement, healing, and grafting					
Hsu 2026[5]	Randomized controlled trial	200 patients	Conventional surgical debridement	Fluorescence-guided vs conventional: residual bacterial area 6.8% vs 30.0%; healing 49.2 vs 63.0 days; reinfection 4% vs 22% (all P<0.001); hospital stay 17.5 vs 21.5 days and antibiotic duration 15.5 vs 18.7 days (both P<0.01)	Single center
Rahma 2022[6]	Pilot randomized controlled trial	56 patients with diabetic foot ulcers	Standard care	12-week healing 45% (95% CI, 26 to 64) with imaging vs 22% (95% CI, 9 to 42) with standard care	Not powered for efficacy; no between-group significance test
Kelso 2024[7]	Retrospective pre/post cohort; 55 long-term care and skilled nursing facilities	167 pressure injuries in 100 Medicare beneficiaries (71 before, 96 after)	Historical standard of care	After vs before adoption: 12-week healing 38.5% vs 22.5% (P=0.007); infection-associated complications 4.2% vs 16.9% (P=0.007)	Nonrandomized historical comparison; adjusted HR for healing 1.80 (95% CI, 0.93 to 3.48; P=0.080), not significant

Study	Design and setting	Sample	Comparator or reference	Principal findings	Key limitations
Oropallo 2026[50]	Prospective single-blinded pilot; CAMP application	10 patients analyzed (18 enrolled)	Fluorescence-negative vs fluorescence-positive wounds	At least 40% area reduction at about 4 weeks in 4 of 5 negative vs 0 of 5 positive (P=0.048)	Small sample; 44% lost to follow-up
Hanson-Viana 2024[51]	Prospective single-center; burns before grafting	38 patients	Graft outcome	Predicted areas of graft loss with sensitivity 86% and specificity 98% (per cm^2 of grafted area)	Small sample
E. Clinical performance data reviewed by FDA (not peer reviewed)					
SnapshotGLO, K242669[29]	Retrospective blinded study; 2 clinical evaluators	40 patients	Predicate device; culture	Positive percent agreement above 88%; accuracy 75% to 82.5%	Not peer reviewed; summary data only
Swift Ray 1, K251678[29]	Prospective accuracy study; 2 sites	53 wounds	Clinical assessment alone	Accuracy 79.2% with imaging plus clinical assessment vs 54.7% with clinical assessment alone (P=0.004); PPV 92.6%; NPV 65.4%	Not peer reviewed; summary data only

Sample sizes are reported as patients, wounds, or assessments, as in the source. Post hoc analyses use data from the FLAAG trial. Comparisons list the imaging group, or the period after adoption, first. FDA data are taken from the public 510(k) summaries. (LVAD) left ventricular assist device; (NPV) negative predictive value; (PPV) positive predictive value.