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PHOTOBIOMODULATION AND LOW-LEVEL LIGHT THERAPY

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Policy scope: This policy addresses the use of photobiomodulation (PBM) therapy and low-level light therapy (LLLT), including monochromatic infrared energy (MIRE) and related light-based therapeutic modalities.

Related policies:

- None

I. MEDICAL NECESSITY CRITERIA

A. Inclusions (Medically Necessary):

Photobiomodulation (PBM) therapy (PBM)/ low- level light therapy (LLLT), is considered medically necessary for:

1. The prevention and/or treatment of oral mucositis when the following criteria is met:

a. The individual is undergoing cancer therapy associated with an increased risk of oral mucositis, including:
  i. Chemotherapy (CT); and/or
  ii. Radiotherapy (RT); and/or
  iii. Hematopoietic stem cell transplantation (HSCT)

B. Exclusions (Not Medically Necessary / Experimental and Investigational):

Photobiomodulation (PBM), also referred to as low- level light therapy (LLLT), including monochromatic infrared energy (MIRE), and related light-based modalities are not medically necessary for all other indications due to insufficient evidence demonstrating improvement in net health outcomes and are considered experimental, investigational, and/or unproven for all other indications. This includes but is not limited to:

1. Wound Care and Cutaneous ulcers, including but not limited to:
   a. Diabetic ulcers
   b. Venous ulcers
   c. Pressure ulcers

2. **Neurologic conditions**, including but not limited to:
   a. Diabetic neuropathy
   b. Peripheral neuropathy
   c. Bell palsy
   d. Dementia

3. **Lymphedema**

4. **Rheumatologic conditions**, including but not limited to:
   a. Rheumatoid arthritis

5. **Upper extremity conditions**, including but not limited to:
   a. Shoulder conditions, including:
      i. Subacromial impingement
      ii. Rotator cuff tendinopathy (including tendonitis)
      iii. Adhesive capsulitis
      iv. Elbow conditions, including:
         a) Lateral epicondylitis (tennis elbow)
      v. Wrist and hand conditions, including:
         a) Carpal tunnel syndrome

6. **Lower extremity conditions**, including but not limited to:
   a. Heel conditions, including:
      i. Heel pain, including:

a) Achilles tendinopathy (including tendonitis)
b) Plantar fasciitis

b. Knee conditions, including:
i. Osteoarthritic knee pain
ii. General knee pain

7. **General musculoskeletal and soft tissue conditions,** including but not limited to:
   a. Back pain
   b. Neck pain
   c. Temporomandibular joint pain and disorders
   d. Fibromyalgia
   e. Myofascial pain

8. **Other conditions,** including but not limited to:
   a. Chronic pelvic pain
   b. Raynaud phenomenon
   c. Dry age-related macular degeneration (AMD)

9. This determination applies regardless of:
   a. Terminology used to describe the service (e.g., PBM, LLLT, cold laser, MIRE)
   b. Device type (e.g., laser, LED, infrared pad)
   c. Delivery method or setting (facility, outpatient, or home use)

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)
NCD - Infrared Therapy Devices (270.6)
Local Coverage Determinations (LCDs)

CGS Administrators, LLC	LCD - Physical Therapy - Home Health (L33942) LCD - Outpatient Physical and Occupational Therapy Services (L34049) LCD - Infrared Heating Pad Systems (L33825)
First Coast Service Options, Inc.	None Identified
Wellpoint Federal (formerly National Government Services, Inc.)	LCD - Outpatient Physical and Occupational Therapy Services (L33631)
Noridian Healthcare Solutions	LCD - Infrared Heating Pad Systems (L33825)
Novitas Solutions, Inc.	None Identified
Palmetto GBA	None Identified
WPS Insurance Corporation	None Identified

III. BACKGROUND

Photobiomodulation (PBM), also referred to as low-level light therapy (LLLT), is a noninvasive modality that uses red or near-infrared light (generally 600–1000 nm) to influence cellular activity. Treatment may be delivered using lasers, light-emitting diodes (LEDs), or infrared systems. Proposed mechanisms include stimulation of mitochondrial function, increased adenosine triphosphate (ATP) production, modulation of inflammatory mediators, and enhancement of tissue repair processes. Despite biologic plausibility, clinical outcomes vary due to heterogeneity in treatment parameters, including wavelength, dose, and duration (Mussttaf et al., 2019).

Monochromatic infrared energy (MIRE), also referred to as monochromatic phototherapy, is a delivery modality within the broader PBM category. It typically utilizes infrared light around 890 nanometers delivered via flexible diode arrays (on flexible pads) applied to the skin. Proprietary systems such as the Anodyne Therapy System employ this approach (Burke, 2003).

The device has been marketed for potential therapeutic applications such as wound healing, treatment of peripheral neuropathy, and management of lymphedema. Proposed mechanisms include increased local blood flow and reduction in pain, which are attributed by the manufacturer to stimulation of nitric oxide release and subsequent vasodilation. However, these claims are based on theoretical and mechanistic effects, and clinical effectiveness varies depending on the indication and supporting evidence.

Although PBM devices, including MIRE systems, have been cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) pathway for indications such as temporary pain relief, these clearances do not establish clinical effectiveness for specific conditions or demonstrate improvement in net health outcomes (Centers for Medicare & Medicaid Services [CMS], 2026).

Across indications, the evidence base for PBM/LLLT is characterized by heterogeneity in treatment protocols, variability in study design, and generally low certainty of evidence. While benefit is supported in select clinical scenarios, most applications lack consistent, reproducible, and clinically meaningful improvement in outcomes, limiting guideline endorsement (Mussttaf et al., 2019).

Oral Mucositis

Oral mucositis is a common complication of chemotherapy, radiotherapy, and hematopoietic stem cell transplantation (HSCT), characterized by erythema, ulceration, pain, and increased risk of infection. Among evaluated applications of PBM/LLLT, this indication has the most consistent and highest-quality evidence.

Systematic reviews and meta-analyses of randomized controlled trials demonstrate that prophylactic PBM significantly reduces the incidence, severity, and duration of oral mucositis compared with standard care or placebo (Oberoi et al., 2014; Peng et al., 2020). More recent meta-analyses confirm reductions in mucositis severity and associated pain, although variability in treatment protocols and study quality remains (Pedroso et al., 2026; Sánchez-Martos et al., 2023; Cronshaw et al., 2020).

Clinical practice guidelines are aligned with these findings. The Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO) recommend PBM for prevention of oral mucositis in HSCT and head and neck cancer populations (Elad et al., 2020). The Pediatric Oncology Group of Ontario (POGO) similarly supports PBM in pediatric oncology settings (Patel et al., 2021).

Wound Care (Cutaneous Ulcers)

Photobiomodulation (PBM), including low-level light therapy (LLLT), has been investigated as an adjunctive therapy for chronic wound management, including diabetic foot ulcers, venous leg ulcers, and pressure injuries. Proposed mechanisms include stimulation of cellular proliferation, promotion of angiogenesis, enhanced collagen synthesis, and modulation of inflammatory pathways. Despite biologic plausibility, clinical effectiveness has not been consistently demonstrated in well-designed studies.

Systematic reviews and evidence syntheses consistently identify significant limitations in the current evidence base, including heterogeneity in wound types, variability in treatment parameters (e.g., wavelength, energy dose, duration), small sample sizes, and lack of standardized comparators (Mussttaf et al., 2019). More recent systematic reviews

and meta-analyses further reinforce these findings. A 2024 meta-analysis evaluating LLLT in skin wounds found improvements in wound size reduction and healing rates; however, authors emphasized the need for higher-quality trials due to methodological limitations and variability across studies (Taha et al., 2024). Similarly, a 2026 meta-analysis of venous leg ulcers reported that photobiomodulation did not demonstrate a statistically significant reduction in ulcer size compared with controls, with substantial heterogeneity and risk of bias limiting confidence in results (Rasul et al., 2026). Additional systematic reviews focusing on diabetic foot ulcers also report inconsistent findings, with potential improvements in wound healing and pain reduction observed in small studies but insufficient evidence to establish long-term effectiveness or optimal treatment parameters (Nurwulandari et al., 2025).

Current society practice guidelines for wound management do not support PBM/LLLT as a standard therapy. The International Working Group on the Diabetic Foot (IWGDF) 2023 guidelines recommend that therapies used to enhance wound healing be supported by high-quality evidence and integrated into multidisciplinary care, including debridement, infection control, and offloading (Chen et al., 2023). The Wound Healing Society (WHS) 2023 update similarly emphasizes evidence-based management and prioritizes established wound care practices, without recommending PBM as standard therapy (Lavery et al., 2024). For pressure injuries, the National Pressure Injury Advisory Panel (NPIAP), European Pressure Ulcer Advisory Panel (EPUAP), and Pan Pacific Pressure Injury Alliance (PPPIA) guidelines emphasize pressure redistribution, nutritional optimization, and evidence-based wound care practices as the foundation of treatment, without inclusion of PBM/LLLT as a recommended modality (NPIAP/EPUAP/PPPIA, 2025).In alignment with current evidence and guideline recommendations, PBM/LLLT is not established as an effective or standard therapy for chronic cutaneous ulcers.

Neurologic Conditions

Photobiomodulation (PBM), including low-level light therapy (LLLT) and monochromatic infrared energy (MIRE), has been investigated for neurologic conditions based on proposed mechanisms such as improved microcirculation, modulation of inflammation, and promotion of nerve regeneration. Despite these theoretical effects, the clinical evidence supporting PBM in neurologic disorders remains inconsistent and limited in quality.

Peripheral Neuropathy

PBM has been most extensively evaluated in diabetic peripheral neuropathy and related neuropathic pain conditions. Earlier high-quality evidence, including a meta-analysis by Robinson et al. (2017), demonstrated no significant improvement in tactile sensitivity or neuropathic symptoms compared with sham treatment, highlighting a lack of consistent clinical benefit. Subsequent studies and systematic reviews continue to demonstrate inconsistent findings, with variability in treatment protocols, outcome measures, and study design limiting the reliability and reproducibility of results.

More recent literature further reinforces these limitations. A systematic review evaluating PBM in diabetic peripheral neuropathy reported improvements in pain and nerve conduction outcomes in some studies; however, findings were based on small, heterogeneous trials with limited methodological rigor, preventing definitive conclusions regarding effectiveness (Korada et al., 2023). Mechanistic and translational reviews similarly note that while PBM demonstrates biologic plausibility and favorable preclinical results, clinical evidence remains insufficient and requires more rigorous randomized trials with standardized protocols (Martins et al., 2025).

Randomized controlled trials also demonstrate inconsistent outcomes. For example, a sham-controlled trial evaluating monochromatic infrared energy (MIRE) found no clear, reproducible improvement in objective measures such as intraepidermal nerve fiber density despite some quality-of-life changes, raising questions regarding clinical relevance and durability of effect (Rastogi et al., 2021). Additional randomized studies of alternative physical modalities for diabetic neuropathy similarly demonstrate variable outcomes and lack of consistent superiority over standard care, further emphasizing the challenges in establishing meaningful clinical benefit (Sahba et al., 2022). Collectively, the evidence for PBM and related modalities in neuropathy is characterized by low certainty, inconsistent clinical outcomes, and lack of standardized treatment approaches, with no clear demonstration of durable or clinically meaningful benefit.

Bell Palsy (Idiopathic Facial Nerve Paralysis)
Photobiomodulation (PBM), including low-level light therapy (LLLT), has been evaluated as a potential adjunct to conventional therapy for Bell palsy. Available evidence from systematic reviews and meta-analyses is mixed and limited, with some small, randomized trials suggesting improvements in facial nerve function, particularly when used in conjunction with exercise therapy or standard care. However, findings across studies are inconsistent and not consistently replicated across validated functional outcome measures.

A recent scoping review (Takizawa et al., 2024) reported that LLLT may be associated with improvements in certain facial nerve outcomes; however, these results were not consistently significant across key clinical endpoints, and the overall evidence base was limited by small sample sizes, heterogeneity in treatment protocols, and variability in study design. A systematic review similarly indicated that while LLLT may demonstrate benefit in selected studies, primarily as an adjunct, lack of standardized dosing parameters, inconsistency in methodology, and variability in study quality limit generalizability and reproducibility exist (Javaherian et al., 2020).

Meta-analyses evaluating laser therapy for Bell palsy further highlight moderate heterogeneity and a lack of high-quality randomized controlled trials, preventing definitive conclusions regarding clinical effectiveness (Lin et al., 2024). Overall, the current body of evidence is inconsistent and of low certainty, with insufficient demonstration of clinically meaningful or durable improvement in facial nerve recovery

compared with standard therapy alone. PBM has not established a reliable or reproducible benefit and remains investigational for this indication.

Dementia and Central Nervous System Disorders
PBM has also been explored in central nervous system (CNS) conditions, including dementia, using transcranial or intranasal delivery techniques. While preclinical studies suggest neuroprotective mechanisms—such as enhanced mitochondrial activity and reduced oxidative stress—clinical evidence remains preliminary.

Systematic reviews indicate that although early clinical studies report potential improvements in cognitive and behavioral outcomes, these findings are based on small, uncontrolled or exploratory trials with limited methodological rigor (Salehpour et al., 2021). More recent reviews of PBM in CNS disorders confirm that clinical translation remains inconsistent, with outcomes highly dependent on treatment parameters, delivery methods, and study design (Cronshaw et al., 2026). Additional reviews of PBM in aging and cognitive impairment similarly conclude that evidence is heterogeneous and insufficient to support routine clinical use, particularly in the absence of large, well-controlled trials (Rodríguez-Fernández et al., 2024). PBM for dementia and related neurologic conditions remains investigational, with insufficient high-quality evidence demonstrating meaningful cognitive or functional benefits.

Lymphedema
Photobiomodulation (PBM), including low-level light therapy (LLLT), has been proposed as a treatment to reduce lymphatic obstruction, fibrosis, and tissue inflammation in individuals with lymphedema. Proposed mechanisms include stimulation of lymphangiogenesis, reduction of inflammatory mediators, and improved lymphatic flow. Despite these theoretical benefits, recent evidence demonstrates that clinical outcomes remain heterogeneous and inconsistent, with insufficient high-quality data supporting sustained or clinically meaningful benefit.

Recent systematic reviews and meta-analyses consistently report mixed and inconclusive findings. An overview of systematic reviews found that, although PBM may provide short-term symptom improvement, the overall certainty of evidence remains low due to variability in study design, laser parameters, and outcome measures (Wang et al., 2022). Additional systematic reviews similarly report that while PBM may reduce limb volume or improve symptoms in some patients, methodological limitations and inconsistency across trials prevent definitive conclusions regarding clinical effectiveness (Mahmood et al., 2022).

More recent meta-analyses reinforce these limitations. A 2023 systematic review and meta-analysis demonstrated variable outcomes across photobiomodulation regimens, with differences in dosing, technique, and comparators contributing to significant heterogeneity and limiting generalizability (Chiu et al., 2023). Similarly, a 2024 meta-analysis evaluating LLLT for breast cancer-related lymphedema reported improvements

in select outcomes but emphasized substantial heterogeneity, risk of bias, and limited overall strength of evidence (Hussein et al., 2024).

Collectively, these findings indicate that although PBM may provide modest, short-term improvements in select outcomes, results are inconsistent, not reproducible across studies, and lack evidence of durable or clinically meaningful benefit. Variability in treatment protocols, small sample sizes, and methodological limitations further reduce confidence in the evidence base.

The International Society of Lymphology (ISL) consensus document (2020) does not include PBM/LLLT as a standard treatment modality (International Society of Lymphology, 2020). Recommended first-line management continues to focus on complete decongestive therapy, including compression therapy, manual lymphatic drainage, exercise, and skin care, all of which are supported by stronger and more consistent evidence. Overall, evidence is insufficient to demonstrate clinically meaningful or durable benefits.

Rheumatologic Conditions (Rheumatoid Arthritis)
Photobiomodulation (PBM), including low-level light therapy (LLLT), has been evaluated as a potential anti-inflammatory and analgesic modality in rheumatoid arthritis (RA). Proposed mechanisms include modulation of inflammatory cytokines, improved microcirculation, and reduction of oxidative stress. Despite these biologic effects, clinical evidence supporting PBM in RA remains inconsistent and of limited clinical significance. Systematic reviews evaluating PBM across inflammatory and musculoskeletal conditions demonstrate heterogeneous findings and low-certainty evidence, largely driven by variability in treatment parameters, inconsistent study quality, and lack of standardized protocols (Mussttaf et al., 2019).

A more recent systematic review and meta-analysis (Lourinho et al., 2023) evaluated 18 randomized controlled trials (n=793) examining the use of LLLT in adults with rheumatoid arthritis. Across studies, treatment durations ranged from 4 weeks to 6 months, with considerable variability in intervention protocols, comparators, and outcome measures. Pooled analyses of key outcomes—including pain, morning stiffness, handgrip strength, functional status, inflammatory markers, and disease activity—were based on small subsets of studies (typically 2–4 studies per outcome) and demonstrated no statistically significant differences between LLLT and control groups. Notably, 17 of the 18 trials were assessed as having a high risk of bias, and the overall certainty of evidence was rated as low, substantially limiting confidence in the findings (Lourinho et al., 2023).

Importantly, current rheumatology guidelines do not support PBM as a treatment for rheumatoid arthritis. The American College of Rheumatology (ACR) 2021 guideline emphasizes early and aggressive use of disease-modifying antirheumatic drugs (DMARDs), biologic therapies, and targeted synthetic agents as the standard of care to

control disease activity and prevent joint damage (Fraenkel et al., 2021). PBM/LLLT is not included as a recommended therapy, reflecting the absence of high-quality evidence demonstrating improvement in disease activity, function, or long-term outcomes. Overall, although PBM demonstrates biologic plausibility and may provide limited short-term symptomatic relief, the available evidence is heterogeneous, low certainty, and not clinically robust, with insufficient demonstration of sustained or clinically meaningful benefit. PBM/LLLT is therefore not considered an established therapy for rheumatoid arthritis.

General Musculoskeletal and Soft Tissue Conditions

Upper Extremity Conditions

Photobiomodulation (PBM), including low-level light therapy (LLLT), has been evaluated in a range of upper extremity musculoskeletal and neurologic conditions as a potential anti-inflammatory and analgesic modality. Despite biologic plausibility, the highest-quality evidence from randomized controlled trials (RCTs) and systematic reviews demonstrates inconsistent and low-certainty clinical benefit across indications. Systematic reviews of randomized controlled trials evaluating LLLT for subacromial impingement syndrome report inconsistent effects on pain and function, with no reproducible benefit compared with exercise therapy or standard rehabilitation (Castaldo et al., 2023).

High-quality meta-analysis of randomized controlled trials specific to rotator cuff tendinopathy further reinforces these findings. A recent systematic review and meta-analysis (Lin et al., 2026) evaluated laser therapy for pain and disability in rotator cuff disorders and found variable treatment effects across studies, with outcomes influenced by differences in treatment parameters and study design. Despite some reported improvements in pain or function, results were inconsistent and not uniformly clinically meaningful, and heterogeneity across trials limited confidence in pooled estimates (Lin et al., 2026).

Similarly, meta-analyses evaluating LLLT for adhesive capsulitis demonstrate variable improvements in pain and range of motion; however, these findings are not consistently superior to conventional therapy, and results depend heavily on treatment protocols and adjunct interventions (Mulyadi et al., 2025).

Systematic reviews and meta-analyses evaluating low-level laser therapy (LLLT) for lateral epicondylitis demonstrate mixed and inconsistent findings. An umbrella review of systematic reviews reported that while some studies show improvements in pain and function, results vary substantially across trials and are influenced by differences in dosing parameters, treatment protocols, and study quality (Mamais et al., 2018).

More recent meta-analytic evidence further supports these limitations. A network meta-analysis of randomized controlled trials found no significant improvement in pain

outcomes compared with placebo across available interventions, with exercise-based therapy demonstrating more consistent benefit than adjunct modalities such as laser therapy (Lowdon et al., 2024).

Randomized controlled trial data show that PBM may produce short-term reductions in pain and functional improvement; however, these findings are limited by small sample sizes and short follow-up durations, and do not establish durable or clinically meaningful benefit (de Oliveira et al., 2025). Overall, the available evidence is characterized by heterogeneity, variable methodological quality, and lack of reproducibility, with inconsistent findings across systematic reviews and randomized trials. These limitations preclude definitive conclusions regarding clinical effectiveness.

Across shoulder conditions, limitations include heterogeneity in dosing parameters, small sample sizes, and inconsistent comparators, which reduce the reliability and generalizability of findings.

High-quality Cochrane systematic review data indicates that evidence is insufficient to determine whether LLLT provides clinically meaningful benefit for carpal tunnel syndrome, with most trials showing no consistent improvement compared with placebo or other conservative treatments, and overall certainty rated as low to very low (Rankin et al., 2017).

Current orthopedic and rehabilitation guidelines do not support PBM/LLLT as a standard treatment modality for upper extremity conditions.

- Rotator cuff and shoulder conditions: Clinical practice guidelines from the American Physical Therapy Association (APTA) and American Academy of Orthopaedic Surgeons (AAOS) emphasize exercise therapy, manual therapy, and rehabilitation strategies as primary management, without inclusion of PBM/LLLT as a recommended modality (AAOS, 2025; APTA, 2025).
- Carpal tunnel syndrome: Clinical guidelines prioritize splinting, corticosteroid injection, rehabilitation, and surgical decompression for appropriate cases; PBM is not recommended due to insufficient evidence (AAOS, 2024; Erickson et al., 2026)
- Lateral epicondylitis: Standard care focuses on activity modification, physical therapy, and injection-based therapies, with no recommendation for PBM.

Lower Extremity Conditions

PBM has been evaluated for lower extremity tendinopathies, including Achilles tendinopathy and plantar fasciitis. Systematic reviews suggest that PBM may provide short-term pain reduction, but evidence is limited by heterogeneity, small study sizes, and lack of long-term follow-up.

More recent meta-analyses conclude that while there may be modest analgesic benefits, improvements in functional outcomes are inconsistent and evidence quality is low (Khalilizad et al., 2024). Clinical significance remains uncertain, particularly when compared with established therapies such as eccentric exercise and orthotics. There is no evidence that infrared light therapy or low-level light therapy is any more effective than other heat modalities in the symptomatic relief of musculoskeletal pain (Stausholm et al (2022).

Low-level laser therapy (LLLT) has been evaluated for Achilles tendinopathy in randomized controlled trials and systematic reviews; however, findings are inconsistent and of low certainty. A systematic review and meta-analysis of randomized trials found no significant effect of photobiomodulation on pain outcomes compared with control, with overall evidence graded as low to very low quality (Rocha et al., 2022). Broader meta-analyses of lower extremity tendinopathies similarly demonstrate that, while modest short-term reductions in pain may occur, these effects are variable, dependent on treatment parameters, and not consistently observed across studies (Naterstad et al., 2022).

These findings are consistent with earlier evidence, which identified a limited number of small randomized trials demonstrating short-term pain improvements when LLLT was combined with eccentric exercise, but no sustained benefit at longer follow-up and no consistent improvement in functional outcomes, with overall evidence graded as low to very low certainty (Martimbianco et al., 2020).

These findings are further supported by more recent systematic reviews and randomized controlled trials demonstrating no consistent or clinically meaningful benefit, particularly when LLLT is evaluated as an adjunct to evidence-based exercise therapy. Collectively, the available evidence remains heterogeneous and of low certainty, with inconsistent findings across studies and no demonstration of durable improvement in pain or function. Accordingly, the evidence is insufficient to support clinically meaningful or sustained benefit and does not support the routine use of LLLT for Achilles tendinopathy (Martimbianco et al., 2020).

More recent randomized controlled trials further reinforce these limitations. Trials comparing eccentric exercise with and without low-level light therapy (LLLT) demonstrate no additional clinical benefit from the addition of laser therapy, with observed improvements attributable to exercise alone (Shriya et al., 2024). Similarly, a multi-arm randomized trial found that the addition of photobiomodulation to standard treatment strategies did not improve outcomes compared with exercise-based therapy, indicating no meaningful incremental benefit (Tenforde et al., 2025).

Overall, the evidence base is characterized by small sample sizes, methodological heterogeneity, and inconsistent findings, with no demonstration of durable or clinically

meaningful benefit. Accordingly, the available evidence is insufficient to support the routine use of LLLT for Achilles tendinopathy.

Low-level laser therapy (LLLT), also referred to as photobiomodulation, has been evaluated as a noninvasive treatment option for plantar fasciitis, primarily for its potential analgesic and anti-inflammatory effects. A recent systematic review (Yadav et al., 2025) identified a limited number of eligible clinical trials and demonstrated that LLLT may be associated with reductions in pain scores compared with baseline, suggesting a potential short-term benefit; however, findings were inconsistent, and the evidence base was limited by small sample sizes and heterogeneity in treatment parameters such as wavelength, dose, and duration. More recent systematic reviews and meta-analyses further highlight these limitations.

A 2023 meta-analysis of randomized controlled trials found that photobiomodulation therapy may improve pain intensity in the short term, either alone or in combination with exercise, but demonstrated uncertain and inconsistent effects on functional outcomes, with no clear evidence of clinically meaningful improvement in disability (Ferlito et al., 2023). Similarly, a 2026 meta-analysis including 13 trials reported that while laser therapy showed modest improvement in certain measures such as heel tenderness, there were no significant improvements in overall pain, functional outcomes, or fascial thickness, and results were characterized by high heterogeneity across studies (Ortiz-Romero et al., 2026).

Across the literature, variability in study design, lack of standardized treatment protocols, and inconsistent comparator groups limit the ability to draw definitive conclusions. Although LLLT appears to be well tolerated with minimal reported adverse effects, the current body of evidence demonstrates inconsistent and low-certainty results, with benefits largely confined to short-term pain reduction and insufficient evidence supporting durable or clinically meaningful improvement. As such, the available data do not establish consistent clinical effectiveness for the routine use of LLLT in the management of plantar fasciitis.

Knee Pain and Osteoarthritis

Photobiomodulation (PBM), including low-level light therapy (LLLT), has been extensively evaluated for knee osteoarthritis (KOA) as a potential analgesic and anti-inflammatory modality. Despite biologic plausibility, clinical evidence supporting PBM in KOA remains inconsistent and of low certainty, with limited demonstration of clinically meaningful functional benefit.

Systematic reviews and meta-analyses examining PBM in knee osteoarthritis demonstrate variable effects on pain with limited or inconsistent improvements in function. A network meta-analysis of randomized controlled trials reported that both LLLT and laser therapy combined with exercise may reduce pain; however, findings were heterogeneous and dependent on treatment parameters, and superiority over

standard exercise-based therapy was not consistently demonstrated (Khalilizad et al., 2024).

Randomized controlled trial evidence further highlights these limitations. A placebo-controlled trial evaluating LLLT combined with strength training found that both treatment and control groups experienced significant pain reduction, with no consistent differences in primary outcomes. While some secondary measures, such as reduced analgesic use or improved performance suggested a possible adjunctive effect, these findings were limited and did not demonstrate clear, clinically meaningful benefit (Stausholm et al., 2022).

Earlier randomized controlled trials and long-term follow-up studies similarly report modest or inconsistent improvements in pain without durable functional benefit, particularly when LLLT is used as an adjunct to exercise-based rehabilitation (Alfredo et al., 2018). Across studies, substantial variability in dosing parameters, treatment duration, and outcome measures contribute to inconsistent and non-reproducible findings.

More broadly, systematic reviews across musculoskeletal conditions consistently identify heterogeneity in treatment protocols, small sample sizes, and methodological limitations, resulting in low to very low certainty of evidence and preventing definitive conclusions regarding clinical effectiveness.

Importantly, current clinical practice guidelines do not support PBM as a standard therapy for knee osteoarthritis. The American Academy of Orthopaedic Surgeons (AAOS) guidelines emphasize exercise therapy, weight management, pharmacologic interventions, and injections as primary management strategies and do not include PBM/LLLT as a recommended modality (AAOS, 2021).

Overall, although PBM may provide modest short-term reductions in pain, the available evidence is heterogeneous, low certainty, and not clinically robust, with insufficient demonstration of sustained or meaningful improvement in functional outcomes or quality of life (AAOS, 2021). PBM/LLLT is therefore not considered an established therapy for knee osteoarthritis.

Back Pain and Neck Pain

Photobiomodulation (PBM), including low-level light therapy (LLLT), has been evaluated for chronic low back pain and neck pain as a potential analgesic modality. While some randomized controlled trials and meta-analyses report short-term reductions in pain, the overall evidence remains inconsistent, with limited or no sustained improvement in function or disability outcomes.

A systematic review and meta-analysis of randomized controlled trials found that LLLT was associated with modest short-term reductions in pain, particularly under specific

dosing conditions; however, these effects were not consistently observed across studies and were not sustained over longer follow-up periods (Glazov et al., 2023). Similarly, a systematic review of randomized trials in chronic pain conditions, including musculoskeletal pain, reported that while PBM may provide analgesic effects, findings were heterogeneous and limited by variability in treatment protocols and follow-up duration, restricting clinical applicability (Ferreira et al., 2026).

Randomized controlled trials further reinforce these findings, with improvements in pain often observed in both PBM and comparator groups, suggesting limited incremental benefits attributable to PBM beyond standard therapy (Glazov et al., 2023; Ferreira et al., 2026). Overall, the evidence base is characterized by heterogeneity in dosing parameters, variability in outcome measures, and methodological limitations, resulting in low to moderate certainty of evidence and lack of consistent, clinically meaningful benefit.

Importantly, current clinical practice guidelines do not support PBM/LLLT as a standard treatment for low back or neck pain. The American College of Physicians (ACP) recommends nonpharmacologic interventions such as exercise therapy, multidisciplinary rehabilitation, acupuncture, and mindfulness-based therapy as first-line management (Qaseem et al., 2017; Qaseem et al., 2020). Similarly, the North American Spine Society (NASS) and National Institute for Health and Care Excellence (NICE) guidelines emphasize exercise therapy, functional restoration, and pharmacologic management, and do not include PBM/LLLT as a recommended modality (NICE, 2016; NASS, 2020).

Temporomandibular Joint Disorders

Photobiomodulation (PBM), including low-level light therapy (LLLT), has been evaluated for temporomandibular disorders (TMD) primarily for pain reduction and functional improvement. While several systematic reviews and meta-analyses report statistically significant reductions in pain and improvements in jaw function, the clinical significance of these findings remains uncertain due to substantial heterogeneity and methodological limitations.

A large systematic review (Hanna et al., 2021) including 44 randomized controlled trials identified a moderate reduction in pain intensity with LLLT compared to comparators; however, heterogeneity was high (I^2=78%), and overall risk of bias varied, with a significant proportion of studies rated as high risk. Similarly, a meta-analysis of 28 RCTs found statistically significant improvements in pain and jaw mobility but noted substantial heterogeneity (I^2 up to 93%) and variability in laser parameters, limiting confidence in the results (Zhang et al., 2023).

A physiotherapy-focused systematic review also demonstrated statistically significant improvements in pain and maximum mouth opening; however, the overall certainty of evidence was rated as low to critically low, with limited reporting of study size and methodological quality (Arribas-Pascual et al., 2023).

Randomized controlled trial evidence remains limited. A recent RCT comparing LLLT, placebo, and standard therapy found that all groups improved significantly, with no differences between treatment arms, suggesting that observed improvements may reflect the natural course of disease or the effects of standard therapy rather than a specific treatment effect (Chamani et al., 2024).Collectively, the evidence suggests that while PBM may be associated with short-term improvements in pain, findings are inconsistent, highly variable, and not clearly clinically meaningful or reproducible.

Importantly, current clinical practice guidelines do not support PBM/LLLT for TMD. A BMJ Rapid Recommendations guideline based on systematic review and GRADE methodology issued a conditional recommendation against the use of low-level laser therapy, citing uncertain benefits and low-certainty evidence, and instead emphasized conservative, multimodal management approaches (e.g., exercise therapy, manual therapy, cognitive behavioral therapy) (Busse et al., 2023).

Overall, the available evidence is characterized by heterogeneity, risk of bias, and lack of durable benefit, and PBM/LLLT is not considered an established therapy for temporomandibular disorders.

Fibromyalgia

PBM has also been evaluated as a treatment modality for fibromyalgia, primarily for pain reduction and improvement in global symptoms. A systematic review and meta-analysis of RCTs (Yeh et al., 2019) demonstrated statistically significant improvements in pain severity, Fibromyalgia Impact Questionnaire (FIQ) scores, fatigue, stiffness, and psychological outcomes compared with placebo. However, these findings must be interpreted cautiously.

The included trials were characterized by low-to-moderate methodological quality, with common limitations including inadequate blinding, unclear allocation processes, and reliance on subjective outcome measures, increasing the risk of performance and detection bias. Substantial heterogeneity was also observed, driven by variation in laser parameters, treatment duration, and concomitant therapies. Importantly, when LLLT was evaluated as an adjunct to exercise therapy, no additional benefit beyond exercise alone was consistently demonstrated, suggesting limited incremental effectiveness. Long-term outcomes were also poorly assessed, with minimal follow-up data available beyond short-term treatment periods.

Overall, while photobiomodulation (PBM) may demonstrate statistically significant short-term symptom improvements, the evidence is heterogeneous and limited in quality and is insufficient to establish durable or clinically meaningful benefit.

Current clinical practice guidelines for fibromyalgia emphasize multidisciplinary management, including physical activity, education, cognitive behavioral therapy, and pharmacologic interventions. EULAR recommendations for fibromyalgia similarly

emphasize these approaches and do not include PBM/low-level light therapy (LLLT) as a recommended treatment modality (Macfarlane et al., 2017). PBM/LLLT is therefore not supported due to insufficient high-quality and reproducible evidence.

Other Conditions

Chronic Pelvic Pain
Photobiomodulation (PBM), including low-level light therapy (LLLT), has been evaluated for chronic pelvic pain in a limited number of randomized controlled trials; however, the evidence base remains small and methodologically heterogeneous. A randomized, placebo-controlled trial demonstrated improvements in pain scores following LLLT; however, no consistent differences were observed between treatment and control groups across key outcomes, and findings were limited by small sample size and short follow-up durations (Keskin et al., 2024).

Overall, the available evidence is characterized by small sample sizes, heterogeneity in treatment parameters, and inconsistent findings, with insufficient data to demonstrate durable or clinically meaningful benefit.

Importantly, clinical practice guidelines do not support PBM/LLLT for chronic pelvic pain. The European Association of Urology (EAU) guidelines emphasize a multidisciplinary, multimodal approach to management, including behavioral, physical, and pharmacologic interventions, without inclusion of PBM as standard therapy (Engeler et al., 2026). Similarly, the American College of Obstetricians and Gynecologists (ACOG) guideline recommends evaluation and management strategies focused on identifying underlying causes, pelvic floor therapy, pharmacologic treatment, and multidisciplinary pain management, and does not include PBM/LLLT as a recommended modality (ACOG, 2020).

Raynaud Phenomenon
Photobiomodulation (PBM), including low-level light therapy (LLLT), has been evaluated for Raynaud phenomenon based on proposed vasodilatory and microcirculatory effects; however, the evidence base is limited and inconsistent. Systematic reviews of non-pharmacologic interventions, including laser therapy, report that while some studies demonstrate reductions in attack frequency and pain, results are heterogeneous and derived from small randomized and crossover trials with variable methodology, limiting confidence in findings (Mahmood et al., 2024)

Earlier systematic reviews and randomized studies similarly suggest possible short-term improvements in symptoms, but outcomes are inconsistent and not reproducible, with substantial variability in treatment protocols and study quality (Khouri et al., 2019). Additionally, broader reviews of PBM across vascular and inflammatory conditions emphasize lack of standardized dosing, limited high-quality trials, and insufficient evidence to establish clinical effectiveness (Glass, 2021). Overall, the available evidence

is characterized by small sample sizes, heterogeneity, and low certainty, with insufficient demonstration of clinically meaningful or durable benefit.

Dry Age-Related Macular Degeneration (AMD)
Photobiomodulation (PBM), also referred to as low-level light therapy, has been proposed as a noninvasive treatment for dry age-related macular degeneration (AMD). The American Academy of Ophthalmology (AAO) reports that PBM was authorized by the U.S. Food and Drug Administration (FDA) based on early clinical evidence, including a randomized study of approximately 100 participants treated with the Valeda Light Delivery System administered in cycles of nine sessions over 3–5 weeks, repeated every four months for up to two years (American Academy of Ophthalmology [AAO], 2025). Patients receiving PBM demonstrated modest improvements in best-corrected visual acuity (approximately 5-letter gain) compared with sham-treated participants (approximately 3-letter gain) and were less likely to develop geographic atrophy; however, a slightly higher rate of conversion to neovascular (wet) AMD was observed. The study was limited by small sample size, incomplete follow-up, and uncertainty regarding long-term real-world outcomes. The AAO notes that PBM shows promise as a noninvasive therapy, but additional data are needed to confirm its safety, durability, and clinical effectiveness (AAO, 2025).

Randomized controlled trial evidence remains limited but evolving. The multicenter, double-masked LIGHTSITE III randomized trial evaluated multiwavelength PBM in patients with intermediate dry AMD and demonstrated statistically significant improvements in visual acuity compared with sham treatment, with mean gains of approximately 5–6 ETDRS letters at follow-up. The study also reported a lower incidence of progression to geographic atrophy in treated patients, although improvement did not consistently meet thresholds for clinically meaningful change and dropout rates approached approximately 25% at longer follow-up intervals (Boyer et al., 2024). Earlier randomized studies, including the multicenter LIGHTSITE II trial, and extension data (LIGHTSITE IIIB), suggest that repeated PBM treatment cycles may produce modest and potentially sustained improvements in visual acuity; however, these findings are derived from relatively small cohorts and remain subject to methodological limitations (Burton et al., 2023).

Systematic reviews and meta-analyses further highlight the limited and heterogeneous evidence base. A 2021 Cochrane systematic review identified only two small randomized controlled trials and concluded that there is low-certainty evidence with no clinically meaningful improvement in visual acuity at 12 months, citing small sample sizes, risk of bias, and inconsistent findings (Henein & Steel, 2021). A more recent systematic review and meta-analysis of randomized clinical trials (Rassi et al., 2024) similarly found statistically significant but clinically modest improvements in visual acuity that did not meet thresholds for meaningful clinical benefit, with ongoing concerns regarding sample size limitations, heterogeneity, and overall risk of bias.

Overall, while emerging randomized trial data (including LIGHTSITE II and III) suggest that PBM may provide small short-term improvements in visual acuity and possible

reductions in disease progression, the current evidence remains limited, heterogeneous, and of low to moderate certainty. Major ophthalmology organizations indicate that additional large-scale, long-term randomized trials are required to establish the safety, durability, and clinical effectiveness of PBM for the treatment of dry AMD (AAO, 2025).

Across evaluated indications, PBM/LLLT demonstrates biologic plausibility but is characterized by heterogeneous evidence, variability in treatment parameters, and generally low certainty of clinical benefit. With the exception of prevention of oral mucositis, where moderate- to high-quality evidence supports use, current clinical practice guidelines consistently prioritize established therapies and do not include PBM/LLLT as a standard treatment modality.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO)	MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy (2020)
Pediatric Oncology Group of Ontario (POGO)	Clinical practice guideline for the prevention of oral and oropharyngeal mucositis in pediatric cancer and hematopoietic stem cell transplant patients: 2021 update
National Institute for Health and Care Excellence (NICE)	Low-level laser therapy for preventing or treating oral mucositis caused by radiotherapy or chemotherapy (2018) Low back pain and sciatica in over 16s: assessment and management (2020)
American Academy of Orthopedic Surgeons (AAOS)	Management of Carpal Tunnel Syndrome (2024) Management of rotator cuff injuries: Evidence-Based Clinical Practice Guideline (2025) Management of Osteoarthritis of the Knee (Non-Arthroplasty) (2021)
Academy of Hand and Upper Extremity Physical Therapy and the Academy of Orthopedic Physical Therapy of the American Physical Therapy Association	Lateral Elbow Pain and Muscle Function Impairments (2022)

Academy of Orthopaedic Physical Therapy (AOPT) of the American Physical Therapy Association (APTA), and the American Physical Therapy Association (APTA)	Rotator Cuff Tendinopathy Diagnosis, Nonsurgical Medical Care, and Rehabilitation: A Clinical Practice Guideline (2025)
European Association of Urology (EAU)	EAU-Guidelines-on-Chronic-Pelvic-Pain-2026.pdf
American College of Obstetricians and Gynecologists (ACOG)	Chronic Pelvic Pain ACOG Practice Bulletin, Number 218 (2020)
International Society of Lymphology (ISL)	The Diagnosis and Treatment of Peripheral Lymphedema: 2020 Consensus Document of the International Society of Lymphology
The American Physical Therapy Association Orthopedics and Hand and Upper Extremity Academies	Clinical Practice Guidelines -Hand Pain and Sensory Deficits: Carpal Tunnel Syndrome: Revision-2026
International Working Group on the Diabetic Foot (IWGDF)	Guidelines on interventions to enhance healing of foot ulcers in people with diabetes (2023)
National Pressure Injury Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance.	Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline (2025)
Wound Healing Society (WHS)	WHS (Wound Healing Society) guidelines update: Diabetic foot ulcer treatment guidelines (2023)
American College of Rheumatology (ACR)	2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
American College of Physicians (ACP)	Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians (2017)
American College of Physicians (ACP) and American Academy of Family Physicians (AAFP)	Nonpharmacologic and Pharmacologic Management of Acute Pain From Non–Low Back, Musculoskeletal Injuries in Adults: A Clinical Guideline from the American College of Physicians and

	American Academy of Family Physicians (2020)
European League Against Rheumatism (EULAR)	EULAR revised recommendations for the management of fibromyalgia (2016)
BMJ Rapid Recommendations	Management of chronic pain associated with temporomandibular disorders: a clinical practice guideline (2023)
North American Spine Society	Diagnosis and Treatment of Low Back Pain - Clinical Guideline (2020)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date
Acculaser Pro4	K023060	03/19/2004
Axiom BioLaser LLLT Series-3	K033015	11/25/2003
Bioptron 2	K032216	02/04/2004
Luminex LL Laser System	K063574	01/29/2007
RianCorp LTU-904	K030295	10/26/2006
Thor DDII 830 CL3 Laser System	K030226	02/10/2003
TerraQuant	K032229	07/25/2005
MuReva Phototherapy System	DEN240077	11/26/2025
FX-635	K190572	06/01/2019
MR4 Laser	K171354	01/13/2018
MR5 ACTIV PRO	K254024	05/19/2026
LightStream™ Low- Level Laser	K081166	04/03/2009
GRT Lite™, Model 8-A	K050668	02/03/2006

MicroLight ML830® Laser Laser System	K010175	02/06/2002
BioFlex™ Professional Therapy System	K081355	12/18/2008
K-LASER	K091497	08/19/2009
Valeda Light Delivery System	DEN230083	11/04/2024

VI. CODING

ICD-10 Codes that may support medical necessity

K12.30 - K12.39 Oral mucositis (ulcerative)

CPT/HCPCS Codes

1011T Photobiomodulation (PBM) therapy of oral cavity, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device

Not Medically Necessary

0552T Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional

0936T Photobiomodulation therapy of retina, single session

97026 Application of a modality to one or more areas; infrared

97037 Application of a modality to 1 or more areas; low-level laser therapy (ie, non-thermal and non-ablative) for post-operative pain reduction

A4639 Replacement pad for infrared heating pad system, each

E0221 Infrared heating pad system

S8948 Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For

more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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SUMMARY OF CHANGES

Deletions:

- Removed outdated and no longer relevant references.

Additions:

- Expanded non-covered indications and organized exclusions by clinical condition.
- Updated background section with current evidence and society guideline recommendations.

Changes:

- Renamed policy from Monochromatic Phototherapy (Anodyne/MIRE/LLLT) to Photobiomodulation (PBM) and Low-Level Light Therapy (LLLT) to align with current clinical terminology and industry standards.
- Revised coverage determination from investigational for all indications to medically necessary for prevention and treatment of oral mucositis in select oncology settings when criteria are met, consistent with MASCC/ISOO and POGO guideline recommendations.
- Reorganized non-covered indications and exclusions into clinically defined categories to improve clarity, consistency, and usability.
- Converted policy to the current template format.

Clarifications:

- Clarified that non-coverage for investigational indications applies regardless of terminology used, device type, or treatment setting.

Past committee review dates: 09/2004, 09/2005, 08/2006, 06/2007, 06/2008, 06/2009, 06/2010, 06/2011, 06/2012, 06/13, 08/14, 08/15, 08/2016, 08/2017, 08/2018, 08/2019, 08/2020, 08/2020, 08/2020, 08/2021, 08/2022, 8/2023, 08/2024, 08/2025,08/2026

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