Policy Number	**MED201.057**
Policy Effective Date	**11/15/2024**

High Intensity Laser Therapy for Chronic Musculoskeletal Pain Conditions and Bell's Palsy

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Related Policies (if applicable)
MED201.045: Low-Level Laser Therapy

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

High intensity laser therapy (HILT) **is considered experimental, investigational, and/or unproven** for all indications, including but not limited to, treatment of chronic musculoskeletal pain and Bell's palsy.

Policy Guidelines

There is no specific procedure code to identify high intensity laser therapy.

Description

High Intensity Laser Therapy
High-intensity laser therapy (HILT) is a Class IV therapeutic non-surgical laser device with a power output >500 mW that is capable of transmitting energy beyond the skin to deep musculoskeletal tissues. HILT is proposed for use in the office setting for various indications including musculoskeletal disorders and Bell's palsy. The devices are intended to provide temporary relief of muscle spasms and minor muscle/joint pain by emitting energy in the infrared spectrum to provide topical heat and tissue temperature elevation which in turn promotes temporary muscle relaxation and increased local blood circulation.

The mechanism of action of HILT to treat chronic pain or Bell's palsy is not clearly understood. Proposed mechanisms of action include having anti-inflammatory effects through photobiomodulation mechanisms by altering inflammatory markers, photothermal effects leading to improved muscle relaxation and extensibility of connective tissue, or analgesic effects through neural inhibition or endorphin mechanisms. (1)

Regulatory Status
Examples of lasers that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process include but are not limited to: Diowave Laser System (formerly Avicenna Laser Technology Inc. K031612; K121363; K091285), ESPT-3X (Lighthouse Technical Innovations, lnc. K083560), K-Laser (K-Laser, USA. K091497), LCT-1000 (LiteCure, LLC. K070400), and OptonPro (Zimmer MedizinSysteme. K141564).

HILT devices have a power output greater than 500 mW and are classified as Class IV lasers by the FDA. (2)

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the

intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

High Intensity Laser Therapy (HILT) for Chronic Musculoskeletal Pain

Clinical Context and Therapy Purpose

The purpose of HILT in individuals who have chronic musculoskeletal pain is to provide a treatment option that is an alternative to conservative treatment or surgery.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with chronic musculoskeletal pain conditions who have not responded to conservative treatment. Conditions proposed as candidates for treatment with HILT include, but are not limited to:

- Chronic low back pain;
- Chronic neck pain;
- Chronic shoulder pain;
- Knee osteoarthritis.

Interventions

The therapy being considered is HILT. HILT devices have a power output greater than 500mW and are classified as Class IV lasers by the U.S. Food and Drug Administration (FDA).

Comparators

Standard care for chronic musculoskeletal pain includes conservative measures such as self-care (weight loss, strengthening exercise), physical therapy, and medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs]). For individuals who fail conservative therapy, a number of interventional therapies are available, which range from minimally invasive procedures (e.g., corticosteroid injections) to surgery.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, health status measures, quality of life (QOL), medication use, and treatment-related morbidity. Specifically, outcomes of interest include reductions in pain and medication usage, and improvement in functional outcomes and QOL.

The effects of HILT for chronic pain conditions are expected to occur from weeks to months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Low Back Pain

Starzec-Proserpio et al. (2022) conducted a systematic review of HILT for chronic pain conditions. (1) Studies with co-interventions were allowed if applied equally to both laser and control groups. There were no limits on study duration or setting. Risks of bias for RCTs were assessed using the Revised Cochrane Collaboration tool. The longest follow-up time was 3 months. Various laser parameters and a large range of doses were used in the included studies. Study results were presented narratively due to heterogeneity across studies in HILT protocols used (e.g., pulsed/continuous emission, scanning/stationary delivery, various wavelengths, and a wide range in energy dose). Subgroup analyses could not be performed to determine optimal HILT parameters.

Chronic nonspecific low back pain was the most frequently studied condition, with 9 of 13 studies covering this indication. Across chronic pain conditions, the reviewers found a greater decrease in pain intensity in the HILT groups relative to the comparators in all trials, assessed with either a numerical rating scale (NRS) or visual analogue scale (VAS). The average changes that occurred after laser treatment both in pain and function surpassed the minimal clinically important differences (MCID) in 12 of the 13 studies. Five studies reported no adverse events. Eight studies did not mention the occurrence or absence of side effects.

The reviewers concluded that overall, the quality of evidence for pain and functional outcomes was moderate, downgrading the level of evidence due to imprecision. They concluded that further high-quality studies are needed prior to recommending the use of HILT in clinical settings, given that only 3 trials had a low risk of bias, 4 studies had some concerns, and 6 trials had a high risk of bias. Allocation concealment and blinding were frequent issues in the available studies, thus increasing the risk of bias. A common issue encountered in the majority of the included studies was the poor reporting of HILT parameters was an issue in a majority of studies. The limited methodological quality of the included studies prevented drawing firm conclusions on the effects of HILT in chronic musculoskeletal pain.

Neck Pain

de la Barra Ortiz et al. (2024) conducted a systematic review and meta-analysis of RCTs of HILT for the management of various neck pain disorders including myofascial pain syndrome, chronic neck pain, cervical spondylosis, cervical radiculopathy, and whiplash syndrome. (3) Five RCTs of chronic neck pain were included. Primary outcomes were pain intensity evaluated through VAS, cervical range of motion (CROM) measurements with goniometry, and neck disability using the Neck Disability Index. the longest duration of follow-up was 3 months.

Subgroup analyses were conducted for chronic neck pain, where the pooled effect size was assessed to be -15.2 mm (95% confidence interval [Cl]: -21.2, -9.1) and -17 mm (95% Cl: -25.2, -10.0), respectively. Compared with placebo, HILT was more effective, leading to an average pain reduction of -18.5 mm (95% Cl: -28.8, -9.0), but placebo laser was only used in studies focused on cervical radiculopathy.

The researchers concluded that the evidence supporting HILT for pain intensity at rest, myofascial pain, chronic neck pain, and cervical radiculopathy was significant but with a very low level of certainty due to risk of bias and heterogeneity of individual studies. The certainty of the overall evidence was downgraded due to high heterogeneity. The most serious methodological limitations of some of the RCTs was related to blinding and allocation concealment.

The systematic review conducted by Starzec-Proserpio et al. (2022), discussed in the low back pain section above, included 2 studies of HILT for chronic neck pain. (1) As noted above, the limited methodological quality of the included studies prevented drawing firm conclusions on the effects of HILT.

Xie et al. (2023) included 8 RCTs in a meta-analysis of HILT for neck pain. (4) Six RCTs delivered HILT plus exercise as the experimental group, 1 delivered HILT alone, and 1 delivered HILT in combination with neurodynamic mobilization/infrared radiation/interferential treatment. The duration of treatment ranged from 2 to 6 weeks.

The risk of bias on blinding of therapists/assessors was high: 88% of included RCTs were unblinded to therapists and 75% were unblinded to assessors. There was high heterogeneity in participant conditions and key HILT parameters among the included RCTs. Long-term follow-up data were not available. Meta-analysis showed moderate-quality evidence that HILT may improve pain intensity and cervical ROM in individuals with neck pain and low-quality evidence showed that HILT had a tendency to improve functional activity. The effect of HILT on QOL was examined in one study only. The reviewers concluded that HILT may be considered as an adjunctive treatment modality for individuals with neck pain, but future studies are needed to identify optimal HILT treatment protocols in various conditions and the retention of any treatment effects. (4)

Knee Osteoarthritis

Cai et al. (2023) conducted a systematic review and meta-analysis of HILT for pain relief in knee osteoarthritis, with searches through September 2022. (5) Nine studies (N = 419, range 20 to 125) were included. Diagnostic methods and duration of symptoms varied across studies, and HILT dose, treatment time, and operation methods were different in individual studies. Two studies (N = 136) provided moderate evidence for HILT for short-term pain relief compared with sham laser therapy. Four studies (N = 160) provided evidence for improved pain scores compared to conventional physiotherapies. Three studies (N = 123) found HILT combined with exercises was more effective than placebo laser or lower-intensity laser combined with exercise. Although meta-analyses were conducted to determine effect sizes, the meta-analyses were highly heterogeneous (heterogeneity greater than 90%). Differences in the included populations (varying grades of knee osteoarthritis, different duration of onset) and intervention methods (different types of HILTs, operating methods, and sites of action) in the included studies preclude drawing conclusions from the body of evidence.

Shoulder Pain

de la Barra Ortiz et al. (2023) conducted a systematic review of HILT for the treatment of frozen shoulder. (6) Five trials met the eligibility criteria and were included in the review and meta-analysis. Meta-analysis found pain intensity was statistically significant in favor of HILT (MD - 2.23 cm; 95% Cl - 3.25 to - 1.22; P < 0.01), although with high heterogeneity (I^2 = 88%). HILT improved shoulder ROM, however adding it to physiotherapy did not improve shoulder flexion, abduction, or external rotation more than conventional physiotherapy.

A RCT of HILT for shoulder pain associated with subacromial impingement syndrome is discussed below. (7)

Randomized Controlled Trial

Yilmaz et al. (2022) reported on a RCT of HILT for shoulder pain, range of motion, and function associated with subacromial impingement syndrome that was not included in any of the systematic reviews discussed above. (7) A total of 72 individuals were randomized to HILT+ exercise or sham HILT (placebo laser) + exercise. HILT (active or placebo) was applied for 15 days (once a day, 5 days a week for 3 weeks). Active and passive range of motion exercises, stretching exercises, and isometric strengthening exercises were applied by a physiotherapist to participants in both groups for 30 minutes once a day, 5 days a week, for 3 weeks. Pain was assessed by VAS after 12 weeks. Shoulder ROM, functional activity, QOL using the SF-36 health survey, and muscle strength measured using an isokinetic device were also assessed.

The study researchers reported improvements from baseline in both groups. Between-group comparisons found greater improvement in active flexion, internal and external rotation ROM measurement, all VAS scores, all SF-36 sub-groups, and most shoulder function parameters in the HILT group compared with the sham HILT group (P< 0.05). Confidence in these results is limited, however, due to serious methodological flaws of the study (Tables 1 and 2). Methodological limitations included: statistically significant differences between groups at baseline on several important factors (age, ROM, VAS measures of pain), suggesting failure of randomization, no description of allocation concealment method, no intention-to-treat analysis

(analysis was reported only for 63/72 completers [87.5%]). Additionally, follow-up at 12 weeks is not sufficient to determine durability of any beneficial effects of treatment.

Table 1. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Yilmaz et al. (2022) (7)					1. 12 weeks not sufficient to determine durability of effects.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 2. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Yilmaz et al. (2022) (7)	1. Significant differences between groups at baseline suggests randomization was inadequate. 3. No information on allocation concealment method.			2. No intention to treat analysis.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Section Summary: High Intensity Laser Therapy for Chronic Musculoskeletal Pain

Although systematic reviews of RCTs have demonstrated statistically and clinically significant improvements in pain and function in individuals receiving HILT, serious methodological limitations of the trials, along with heterogeneity in HILT parameters, cointerventions, and patient characteristics decreases confidence in results and precludes drawing conclusions about the treatment's effectiveness. Additionally, there are no established practice guidelines on the use of HILT in chronic pain disorders and it is unclear where the technology fits in the clinical pathway.

High Intensity Laser Therapy for Bell's Palsy

Clinical Context and Therapy Purpose

The purpose of HILT in individuals with Bell's Palsy is to provide a treatment option that is an alternative to existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with Bell's palsy, a condition in which the muscles on 1 side of the face become weak or paralyzed caused by trauma to the seventh cranial nerve.

Interventions

The therapy being considered is HILT.

Comparators

Standard care for Bell's palsy is conservative therapy (e.g., exercise) and medications, including corticosteroids and antiviral drugs.

Outcomes

General outcomes of interest are improvements in functional outcomes and QOL and a reduction in symptoms and treatment-related morbidity. The effects of HILT to promote healing are expected to occur from weeks to months. Outcomes are assessed using the Facial Disability Index and the House-Brackmann Scale.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Review

In a systematic review of laser treatment for Bell's palsy, Kim et al. (2023) (8) identified only one RCT of HILT, reported by Alayat et al. (2013). (9) Participants (N = 48; 3 groups of 17 individuals each) were randomized to 1 of 3 groups: HILT, low-level laser therapy, or exercise only. Facial exercises and massage were given to all patients. Laser treatment was given 3 times a week to 8 points on the affected side for 6 weeks. At 3- and 6-weeks post-treatment, outcomes were assessed using the Facial Disability Index and the House-Brackmann Scale. Significant improvements in recovery were seen in both laser therapy groups over exercise alone, with the greatest improvement seen with HILT. Significant improvements from baseline in facial disorder index (FDI) scores in the laser group were observed at weeks 3 and 6 ($P < 0.001$) and were greater for the laser groups than exercise alone. Methodological limitations of the trial included a lack of blinding of therapists and outcome assessors, no intention-to-treat analysis, and insufficient duration of follow-up to isolate specific improvements from laser therapy over the natural resolution of the illness.

Section Summary: High Intensity Laser Therapy for Bell’s Palsy

A systematic review of laser treatment for Bell’s palsy found a single RCT, which showed improvement in the laser groups over exercise alone. However limitations in the trial included a lack of blinding or therapists and outcome assessors and insufficient follow-up.

Summary of Evidence

For individuals who have chronic musculoskeletal pain who receive high intensity laser therapy (HILT), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Although systematic reviews of RCTs have demonstrated statistically and clinically significant improvements in pain and function in individuals receiving HILT, serious methodological limitations of the trials, along with heterogeneity in HILT parameters, cointerventions, and

patient characteristics, decreases confidence in results and precludes drawing conclusions about the treatment's effectiveness. Additionally, there are no established practice guidelines on the use of HILT in chronic pain disorders and it is unclear where the technology fits in the clinical pathway. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Bell's palsy who receive HILT, the evidence includes 1 RCT (N=48, in 3 groups of 17) comparing HILT, low level laser therapy, and facial expression exercise after 6 weeks of treatment. Significant improvements in recovery were seen in both laser therapy groups over exercise alone, with the greatest improvement seen with HILT, but study design limitations preclude drawing conclusions. Additionally, because Bell's palsy often improves within weeks and may resolve completely within months, it is difficult to isolate specific improvements from laser therapy over the natural resolution of the illness. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

North American Spine Society

The North American Spine Society (2020) Guidelines on Diagnosis and Treatment of Low Back Pain include the following relevant recommendations: (10)

- It is suggested that the combination of laser therapy (low-level or high level) with exercise provides better short-term relief of pain than either exercise or laser therapy alone. Grade of Recommendation: B
- There is conflicting evidence that the combination of laser therapy with exercise provides better short-term improvement in function compared to exercise or laser therapy alone. Grade of Recommendation: I
- It is suggested that there is no short-term benefit of laser therapy (low-level or high level) when compared with exercise alone. Grade of Recommendation: B

Ongoing and Unpublished Clinical Trials

A currently ongoing trial that might influence this policy is listed in Table 3.

Table 3. Summary of Key Trials

NCT. No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05689788	Effect of High-intensity Laser Therapy in Patients With Chronic Nonspecific Neck Pain. Randomized Clinical Trial	72	Feb 2025

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97039, 97139, 97799
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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10. North American Spine Society (2020). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis & Treatment of Low Back Pain. Available at <https://www.spine.org> (accessed June 18, 2024).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
11/15/2024	New medical document. High intensity laser therapy (HLT) is considered experimental, investigational, and/or unproven for all indications, including but not limited to, treatment of chronic musculoskeletal pain and Bell's palsy. High intensity laser therapy was previously addressed on MED201.045 Low-Level and High-Power Laser Therapy (now Low-Level Laser Therapy).