

<b>2.01.108 High Intensity Laser Therapy for Chronic Musculoskeletal Pain Conditions and Bell's Palsy</b>	
<b>Original Policy Date:</b> October 1, 2024	<b>Effective Date:</b> October 1, 2024
<b>Section:</b> 2.0 Medicine	<b>Page:</b> Page 1 of 12

**Policy Statement**

- I. High Intensity Laser Therapy (HILT) for treatment of chronic musculoskeletal pain is considered **investigational**.
- II. HILT for treatment of Bell's palsy is considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

**Policy Guidelines**

**Coding**  
See the [Codes table](#) for details.

**Description**

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.

**Related Policies**

- Low Level Laser Therapy

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory Status**

Examples of lasers that have been cleared for marketing by the 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, Inc.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 500mW and are classified as Class IV lasers by FDA.<sup>2</sup>

## Rationale

### Background

#### 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.<sup>1</sup>

### Literature Review

Evidence reviews 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 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 review.

#### *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 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 antiinflammatory 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, 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.<sup>1</sup> 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.<sup>3</sup> 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% CI:-21.2,-9.1) and -17 mm (95% CI:-25.2,-10.0), respectively. Compared with placebo, HILT was more effective, leading to an average pain reduction of -18.5 mm (95% CI:-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.<sup>1</sup> 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.<sup>4</sup> 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.<sup>4</sup>

### 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.<sup>5</sup> 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.<sup>6</sup> 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% CI - 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.<sup>7</sup>

### Randomized Controlled Trial

Yilmaz et al (2022) reported 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.<sup>7</sup> 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 and 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 <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
Yilmaz et al (2022) <sup>7</sup>					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.

<sup>a</sup> 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.

<sup>b</sup> 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.

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

<sup>d</sup> 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.

<sup>e</sup> 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 <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Yilmaz et al (2022) <sup>7</sup>	1. Significant differences between groups at baseline suggests randomization was inadequate <sup>3</sup> . 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.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

<sup>b</sup> Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

<sup>d</sup> 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.

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

<sup>f</sup> 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 review.

#### *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)<sup>8</sup>, identified only one RCT of HILT, reported by Alayat et al (2013).<sup>9</sup> 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 posttreatment, 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**

For individuals who have chronic musculoskeletal pain who receive HILT, the evidence includes 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, co-interventions, 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.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### North American Spine Society

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

- 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

### U.S. Preventive Services Task Force Recommendations

Not applicable

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

A currently unpublished trial that might influence this review is listed in Table 3.

**Table 3. Summary of Key Trials**

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

NCT: national clinical trial.

## References

1. Starzec-Proserpio M, Grigol Bardin M, Fradette J, et al. High-Intensity Laser Therapy (HILT) as an Emerging Treatment for Vulvodynia and Chronic Musculoskeletal Pain Disorders: A Systematic Review of Treatment Efficacy. *J Clin Med.* Jun 27 2022; 11(13). PMID 35806984
2. Food & Drug Administration. Laser Products and Instruments. <https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-products-and-instruments>. Accessed June 14, 2024.



3. de la Barra Ortiz HA, Arias M, Liebano RE. A systematic review and meta-analysis of randomized controlled trials on the effectiveness of high-intensity laser therapy in the management of neck pain. *Lasers Med Sci.* May 06 2024; 39(1): 124. PMID 38709332
4. Xie YH, Liao MX, Lam FMH, et al. The effectiveness of high-intensity laser therapy in individuals with neck pain: a systematic review and meta-analysis. *Physiotherapy.* Dec 2023; 121: 23-36. PMID 37812850
5. Cai P, Wei X, Wang W, et al. High-intensity laser therapy on pain relief in symptomatic knee osteoarthritis: A systematic review and meta-analysis. *J Back Musculoskelet Rehabil.* 2023; 36(5): 1011-1021. PMID 37458008
6. de la Barra Ortiz HA, Parizotto N, Arias M, et al. Effectiveness of high-intensity laser therapy in the treatment of patients with frozen shoulder: a systematic review and meta-analysis. *Lasers Med Sci.* Nov 20 2023; 38(1): 266. PMID 37981583
7. Yilmaz M, Eroglu S, Dundar U, et al. The effectiveness of high-intensity laser therapy on pain, range of motion, functional capacity, quality of life, and muscle strength in subacromial impingement syndrome: a 3-month follow-up, double-blinded, randomized, placebo-controlled trial. *Lasers Med Sci.* Feb 2022; 37(1): 241-250. PMID 33400012
8. Kim JH, Goo B, Nam SS. Efficacy of Laser Therapy on Paralysis and Disability in Patients with Facial Palsy: A Systematic Review of Randomized Controlled Trials. *Healthcare (Basel).* Aug 29 2023; 11(17). PMID 37685454
9. Alayat MS, Elsodany AM, El Fiky AA. Efficacy of high and low level laser therapy in the treatment of Bell's palsy: a randomized double blind placebo-controlled trial. *Lasers Med Sci.* Jan 2014; 29(1): 335-42. PMID 23709010
10. North American Spine Society (2020). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis & Treatment of Low Back Pain. <https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf>. Accessed June 18, 2024.

### Documentation for Clinical Review

- No records required

### Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	97039	Unlisted modality (specify type and time if constant attendance)
	97139	Unlisted therapeutic procedure (specify)
	97799	Unlisted physical medicine/rehabilitation service or procedure
HCPCS	None	

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
10/01/2024	New policy.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language,*

*including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT	
BEFORE	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p><b>New Policy</b></p> <p><b>Policy Statement:</b> N/A</p>	<p><b>High Intensity Laser Therapy for Chronic Musculoskeletal Pain Conditions and Bell's Palsy 2.01.108</b></p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. High Intensity Laser Therapy (HILT) for treatment of chronic musculoskeletal pain is considered <b>investigational</b>.</li> <li>II. HILT for treatment of Bell's palsy is considered <b>investigational</b>.</li> </ul>