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## 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 treatment of chronic musculoskeletal pain.

HILT for treatment of Bell's palsy **is considered experimental, investigational, and/or**

unproven.

## 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, 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 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 (QoL), 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 Conditions**

### 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, 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.

### Overview of Systematic Reviews

de la Barra Ortiz, Avila, and Liebano (2024) carried out an umbrella review to assess the methodological quality, reliability, and validity of systematic reviews (SRs) on HILT in musculoskeletal pain management and provide an overview of the current SR landscape. (3) The HILT effects on pain intensity were reported using mean differences (MD) or standardized mean differences (SMD). The average MD and SMD, along with their respective confidence intervals (CI), were estimated and presented based on the aggregate study outcomes. Twenty SRs published through October 2024 were included, 14 of which conducted meta-analyses covering diverse musculoskeletal disorders such as knee osteoarthritis, epicondylalgia, myofascial pain, frozen shoulder, plantar fasciitis, neck, and low back pain. The quality assessment was conducted using the A Measurement Instrument to Assess Systematic Reviews 2 checklist (AMSTAR-2) and the results indicate low or critically low methodological quality for many of the SRs included in this review. HILT's best analgesic effects are observed in frozen shoulder disorder (MD: -2.23 cm; 95% CI: -3.3 to -1.2;  $p < .01$ ), knee osteoarthritis (MD: -1.9 cm; 95% CI: -2.0 to -1.8;  $p < .01$ ), low back pain (MD: -1.9 cm; 95% CI: -2.9 to -1.0;  $p < .01$ ), and myofascial pain (MD: -1.9 cm; 95% CI: -2.6 to -1.2;  $p < .01$ ). Largest effect sizes are for neck pain (SMD: 2.1; 95% CI: 1.2 to 3.0,  $p < .05$ ) and low back pain (SMD: 1.1; 95% CI: 1.4 to 0.8;  $p < .01$ ). The summary of meta-analysis results reported by the SRs for HILT after treatment are reported in Appendix 1a/1b.

### *Musculoskeletal Disorders*

Hassan et al. (2025) conducted a systematic review and meta-analysis on 28 randomized clinical trials (RCT) comprised of 1460 individuals to compare the effectiveness of extracorporeal shock wave therapy (ESWT) with laser therapy (low-level laser therapy [LLLT]) and HILT in treating musculoskeletal disorders. (4) Overall, the results showed that neither laser therapy had significant difference over ESWT in pain, strength, range of motion, nor QoL, however ESWT did demonstrate a marginal statistically significant advantage over LLLT but not HILT in improving functionality. Furthermore, using GRADE (Grading of Recommendations, Assessment,

Development, and Evaluation) certainty rating, all treatment modalities had an equivalent effect in improving pain, strength, range of motion, and QoL in patients with musculoskeletal disorders, while ESWT demonstrated some short-term benefit in functionality over LLLT but not HILT. Notable limitations include, but are not limited to, very low to moderate certainty of evidence (according to GRADE), high-risk of bias, lack of blinding of assessor or participants, and substantial clinical heterogeneity amongst the studies in regard to variations in pathology, treatment protocols, symptoms durations, and study populations.

Saleh et al. (2024) performed a systematic review to evaluate HILT and LLLT to determine if either treatment modality had superiority in treating musculoskeletal disorders. (5) Twelve articles (N=704) were included in the qualitative review but only 2 were used in the meta-analysis. There were no statistical differences between the 2 interventions in pain, electrophysiological parameters, level of disability, QoL, postural sway, or pressure algometer. Due to the large heterogeneity within the studies, regarding population, measured outcomes, and intervention strategies with differences in the duration of application, wavelength, power and frequency, the applicability of these results are severely limited.

#### *Low Back Pain*

One systematic review had been identified (1) and was included in the umbrella review (see Appendix 1a/1b).

#### *Neck Pain*

Three SRs have been identified (de la Barra Ortiz et al. [2024], Xie et al. [2023], and Starzec-Proserpio et al. [2022]) and were included in the umbrella review (see Appendix 1a/1b).

#### *Knee Osteoarthritis*

Khalilzad, Hosseinzade, and Abadi (2024) performed a systematic review and network meta-analysis on pooled evidence from 11 RCTs (N=433) comparing HILT with exercise therapy (ET), LLLT with ET, and placebo with ET in their ability to reduce pain and improve function of patients with knee osteoarthritis. (6) The results of the meta-analysis demonstrated significant improvements in visual analogue scale (VAS) pain and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function scores for both HILT plus ET and LLLT plus ET compared to the control group at weeks 4 and 8. Furthermore, HILT plus ET showed a greater reduction in the VAS pain score (SMD=-1.41; 95% CI: -2.05 to -0.76) and improvement in the WOMAC function score (SMD=-2.20; 95% CI: -3.21 to -1.19) than LLLT plus ET in week 8 but treatment modalities were not significantly different at week 4. Notable limitations include the significant heterogeneity between the studies for certain outcomes, small sample sizes for each individual study, and differences within the irradiation parameters.

One other systematic review had been identified (16) and was included in the umbrella review (see Appendix 1a/1b).

#### *Thumb Pain*

de la Barra Ortiz et al. (2025) conducted a systematic review (N=100; 3 studies) of HILT for the

treatment of De Quervain's tenosynovitis with the primary outcome of change in pain intensity assessed by the VAS or numeric pain rating scale (NPRS). (7) Secondary outcomes include changes in grip or pinching strength and disability, measured with dynamometry and scales such as the disabilities of the arm, shoulder, and hand (DASH) questionnaire. For pain intensity, disability, and grip strength no statistical difference was detected between the HILT and control groups, albeit some of the outcomes did display better numerical values than the control group. Notable limitations include, but are not limited to, small numbers of available studies, small sample sizes within the included studies, and potential bias as there was no blinding of the assessor nor was there a sufficient number of studies to conduct a publication bias analysis.

### *Shoulder Pain*

One systematic review had been identified (17) and was included in the umbrella review (see Appendix 1a/1b).

A RCT of HILT for shoulder pain associated with subacromial impingement syndrome is discussed below. (8)

### Randomized Controlled Trials

#### *Neck Pain*

Yassin et al. (2024) conducted a randomized clinical trial in 32 female participants with active upper trapezius myofascial trigger points who received either high intensity laser therapy (HILT) or dry needling (DN) and were assessed for pain intensity, cervical range of motion, and disability in response to treatment. (9) Outcomes of interest were measured using a VAS for pain intensity, an iPhone inclinometer and goniometer for side bending and rotation of the cervical spine, and the neck disability index (NDI) questionnaire to assess disability. For both treatment modalities, the VAS and NDI were significantly reduced posttreatment ( $p < .001$ ), and the cervical range of motion significantly increased in response to both therapies ( $p < .05$ ). However, there was no significant difference in pain intensity, neck disability index, and the cervical range of motions between the 2 groups ( $p > .05$ ). Notable limitations include, but are not limited to, lack of control group, lack of muscle strength or activity level, the absence of long-term follow-up, and the lack of comparison between DN and HILT in the latent trigger points.

#### *Jaw Pain*

Qataya et al. (2025) enrolled 29 individuals with chronic myogenic temporomandibular disorder (TMD) into a randomized clinical trial to evaluate the effectiveness of Piano level laser therapy using neodymium-doped yttrium aluminum garnet (Nd-YAG) laser and intramuscular epidermal growth factor (EGF) injections for pain alleviation, function, and QoL improvement. (10) Individuals were randomized into 2 cohorts, cohort 1 ( $n=13$ ) received HILT (piano level laser) and cohort 2 received an intramuscular injection of EGF and were assessed for pain reduction using the numerical rating score (NRS), pain free opening (PFO) and unassisted maximum opening measured at baseline, 7-, 14-, 21-days, 1-, and 3-months. Additionally, QoL using OHIP-14 was assessed at baseline, 1-, and 3-months. Both EGF injection and HILT cohorts demonstrated a significant reduction in pain scores ( $p < .000$ ) with a sharp decrease starting at day 7 but no significant differences between the 2 treatment modalities. Likewise, PFO results

were highly similar to NRS results with both therapies significantly increasing in response to treatment ( $p<.0001$ ) at day 7 but displaying no significant differences measured when comparing the 2 treatments. Regarding the effects of these treatment modalities on maximum opening, the results showed that patients receiving HILT had a significant increase ( $p=.007$ ), which was not reported in the cohort that received EGF injections. Intra-group analysis showed a significant improvement in QoL in both treatment groups in response to treatment ( $p=.0001$ ). However, intergroup analysis showed that there was no significant difference between the 2 treatment modalities regarding impact on QoL. Small sample size and insufficient follow-up period limits the interpretability of these results.

### *Elbow Pain*

Bilir et al. (2024) evaluated and compared the short-term efficacies of HILT and focused extracorporeal shockwave therapy (FSWT) on pain, grip strength, and function in 47 patients with lateral epicondylitis. (11) A VAS, quick Disabilities of the Arm, Shoulder, and Hand (QDASH), and hand grip strength test were used to evaluate the patients at baseline, 1-, and 6-weeks after treatment. There were significant improvements in VAS scores, QDASH scores, and grip strength for both treatment options at week 1 and 6 ( $p<.05$ ) but no significant differences were observed between the 2 treatment options. Notable limitations include, but are not limited to, lack of control group, small sample size, absence of long-term follow-up, and lack of blinding.

### *Shoulder Pain*

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 SRs discussed above. (8) 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 range of movement (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) (8)					1. 12-weeks not sufficient to determine durability of effects.
Yassin et al. (2024) (9)			2. Dry needling.		1. 3-weeks not sufficient to determine durability of effects.
Qataya et al. (2025) (10)			2. Intramuscular epidermal growth factor injection.		1. 12-weeks not sufficient to determine durability of effects.
Bilir et al. (2024) (11)			2. Extracorporeal shock wave therapy		1. 6-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) (8)	1. Significant differences between groups at baseline suggests			2. No intention to treat analysis.		



	randomization was inadequate 3. No information on allocation concealment method.					
Yassin et al. (2024) (9)					1. Calculations not reported.	
Qataya et al. (2025) (10)		1. Patients and primary clinician were not blinded.				
Bilir et al. (2024) (11)	3. No information on allocation concealment method.	1. Patients were not blinded.				

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 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.

### Systematic Review

In a systematic review of laser treatment for Bell's palsy, Kim et al. (2023) (12) identified only

one RCT of HILT, reported by Alayat et al. (2013). (13) Participants (N = 48; 3 groups of 17 individuals each) were randomized to 1 of 3 groups: HILT, LLLT, 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

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.

#### **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: (14)

- 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

Current trials that might influence this policy are listed in Table 3.

**Table 3. Summary of Key Trials**

NCT. No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT05689788	Effect of High-intensity Laser Therapy in Patients With Chronic Nonspecific Neck Pain. Randomized Clinical Trial	72	Feb 2025
NCT06651775	Effectiveness of High Intensity Laser Therapy (HILT) in Patients With Chronic Lumbar Radiculopathy Due to Disc Herniation	70	Feb 2025 (recruiting)
NCT06983457	Comparative Effects of Therapeutics Ultrasound and Shockwave Therapy on Pain and Quality of Life in Patients With Chronic Heel Spur Pain. A Randomized Controlled Clinical Trial	41	Feb 2026

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.

<b>CPT Codes</b>	97039, 97139, 97799
<b>HCPCS Codes</b>	None

\*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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## 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
10/15/2025	Document updated with literature review. Removed “for all indications, including but not limited to” and separated coverage statements. Added references 3-11; others updated and/or removed.
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).
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## Appendix

### Appendix 1a. Umbrella Review of Systematic Reviews

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)
Wyszyńska et al. (2018)	NR	NR	NR	NR	NR
Song et al. (2018)	PI at rest (VAS) for back disorders	3	75	70	145
	PI at rest (VAS) for neck disorders	3	154	155	309
	PI at rest (VAS) for shoulder	2	68	68	136
	PI at rest (VAS) for arm/hand	3	71	75	146
	PI (VAS) overall	11	368	368	736
	Back disability	3	75	70	145
	Neck disability	3	154	155	309
	Shoulder disability	2	68	68	136
	Arm/hand disability	2	71	75	146
	Overall disability	10	344	344	688
Alayat et al. (2019)	HILT plus exercise in LBP	1	28	24	52
	HILT plus exercise in NP	2	68	67	135
	HILT plus exercise for PI in spinal disorders overall	3	96	91	187
	HILT plus exercise for disability in LBP	1	28	24	52
	HILT plus exercise for disability in NP	2	68	67	135
	HILT plus exercise for disability in spinal disorders overall	3	96	91	187
	HILT in LBP	1	15	15	30
	HILT in NP	2	68	67	135
	HILT for PI in spinal disorders overall	2	96	91	187
	HILT for disability in LBP	1	15	15	30
	HILT for disability in NP	1	88	88	176
	HILT for disability in spinal disorders overall	2	102	103	205
	HILT plus PT in LBP	4	98	89	187



	HILT plus PT for disability in LBP	4	98	89	187
Song et al. (2020)	PI (VAS)	6	182	152	334
	Stiffness (WOMAC and KSCRS)	4	87	81	168
	Disability/function (WOMAC and KSCRS)	4	87	81	168
Ezzati et al. (2020)	NR	NR	NR	NR	NR
de la Barra et al. (2021)	NR	NR	NR	NR	NR
Stasinopoulos et al. (2021)	NR	NR	NR	NR	NR
de la Barra et al. (2022)	PI at rest (VAS)	3	86	86	172
	PI at rest for 1-month follow-up (VAS)	2	61	61	122
	Cervical flexion (GNM)	2	61	61	122
	Cervical extension (GNM)	2	61	61	122
	Cervical right-side bending (GNM)	2	61	61	122
	Cervical left-side bending (GNM)	2	61	61	122
	Cervical right rotation (GNM)	2	61	61	122
	Cervical left rotation (GNM)	2	61	61	122
Starzec-Proserpio et al. (2022) (1)	PI (VAS, NPRS)	13	NR	NR	NR
	Function/disability (ODI, MODQ, RMQ, PDI, NDI, JFLS-20)	13	NR	NR	NR
Wu et al. (2022)	PI (VAS) HILT vs LLLT	3	65	67	132
	PI (VAS) HILT vs placebo (both with exercise)	7	167	164	331
	Function (WOMAC) HILT vs LLLT	2	35	33	68
	PI (WOMAC) HILT vs placebo (both with exercise)	4	87	81	168
	Stiffness (WOMAC) HILT vs placebo (both with exercise)	4	87	81	168
	Function (WOMAC) HILT vs placebo (both with exercise)	4	87	81	168
	WOMAC overall HILT vs placebo (both with exercise)	5	102	96	198
Xie et al. (2023) (15)	PI: HILT placebo vs HILT	4	113	112	225
	Cervical flexion ROM: HILT placebo vs HILT	4	113	112	225
	Cervical extension ROM: HILT placebo vs HILT	4	113	112	225
	Right side bending ROM: HILT placebo vs HILT	3	93	32	125

	Left side bending ROM: HILT placebo vs HILT	3	93	32	125
	Right rotation ROM: HILT placebo vs HILT	3	93	32	125
	Left rotation ROM: HILT placebo vs HILT	3	93	32	125
	Cervical ROM overall: HILT placebo vs HILT	12	598	592	1190
	Functional activity: HILT placebo vs HILT	3	83	83	166
	QoL: HILT placebo vs HILT	NR	NR	NR	NR
Silva et al. (2023)	NR	NR	NR	NR	NR
Cai et al. (2023) (16)	PI after treatment (VAS): HILT vs LLLT	2	69	67	136
	PI after treatment (VAS): HILT vs CPT	4	80	80	160
	PI after treatment (VAS): HILT+TE vs LLLT+TE	3	67	60	127
	PI overall	8	212	207	419
Arroyo-Fernández et al. (2023)	PI after treatment (VAS): HILT vs sham/control	28	537	514	1051
	PI after treatment (VAS): HILT vs other intervention	29	752	842	1594
	PI after treatment (VAS) overall	67	1289	1456	2745
	Functionality after treatment (VAS): HILT vs sham/control	24	460	535	995
	Functionality after treatment: HILT vs other intervention	23	592	697	1289
	Functionality after treatment overall	47	1052	1323	2375
	ROM after treatment: HILT vs sham/control	15	331	384	715
	ROM after treatment: HILT vs other intervention	9	165	242	407
	ROM after treatment overall	24	496	626	1122
	Strength after treatment: HILT vs sham/control	4	80	87	167
	Strength after treatment: HILT vs other intervention	5	105	116	221
	Strength after treatment overall	9	185	203	388
	Physical functioning (SF-36)	6	117	140	257
	Role physical (SF-36)	6	117	140	257

	Bodily pain (SF-36)	6	117	140	257
	General health (SF-36)	6	117	140	257
	Vitality (SF-36)	6	117	140	257
	Social functioning (SF-36)	6	117	140	257
	Role emotional (SF-36)	6	117	140	257
	Mental health (SF-36)	6	117	140	257
de la Barra et al. (2023) (17)	PI at rest (VAS)	5	109	118	227
	PI at rest for 3-month follow-up (VAS)	4	74	83	157
	Shoulder flexion (GNM)	4	94	103	197
	Shoulder external rotation (GNM)	4	9	103	197
	Shoulder abduction (GNM)	3	61	70	131
	Shoulder disability (SPADI)	3	74	83	157
de la Barra et al. (2023) (17)	PI at rest (VAS)	6	168	168	336
	PI at first steps (VAS)	3	92	94	186
	PI after walking (VAS)	2	76	78	154
	PI at sitting (VAS)	2	76	78	154
	PI at rest for 3-month follow-up (VAS)	4	86	86	172
	PI at rest (FAOS subscale)	3	81	83	164
	Daily life activities (FAOS subscale)	3	81	83	164
	Symptoms (FAOS subscale)	3	81	83	164
	Performance of sports & recreation activities (FAOS subscale)	3	96	98	194
	QoL (FAOS subscale)	3	81	83	164
ElMeligie et al. (2023)	PI at rest (VAS)	3	138	144	282
	PI during activities (VAS)	5	94	99	193
	PI (VAS) overall	8	232	243	475
	Handgrip strength (DNM)	5	138	144	282
	Mental component of QoL	4	123	129	252
Abdildin et al. (2023)	PI at rest (VAS)	2	46	41	87
	PI at rest (VAS) 3-month follow-up	3	66	61	127
	PI (VAS) overall	5	112	102	214
	Disability (ODI) after treatment	5	46	41	87
	Disability (RMQ) after treatment	4	66	61	127
	Disability (ODI and RMQ) overall	9	112	102	214
Tang et al.	PI at rest (VAS)	3	150	155	305

(2023)	Handgrip strength (DNM)	5	120	124	244
	Disability (DASH)	3	75	79	154
	QoL (SF-36)	2	44	45	89
de la Barra et al. (2024) (18)	PI at rest (VAS)	17	566	540	1106
	PI at movement (VAS)	2	68	67	135
	PI at rest (VAS) 3-month follow-up	3	154	155	309
	Disability (NDI)	12	397	404	801
	Cervical flexion (GNM)	9	271	251	522
	Cervical extension (GNM)	9	271	251	522
	Cervical right-side bending (GNM)	9	251	251	502
	Cervical left-side bending (GNM)	9	251	251	502
	Cervical right rotation (GNM)	8	209	209	418
	Cervical left rotation (GNM)	8	209	209	418

Adapted from de la Barra et al. (2024), Lasers in Medical Science (2024) 39:290. (3)

CPT: conventional physical therapy; DASH: the disabilities of the arm, shoulder and hand questionnaire; DNM: dynamometry; FAOS: foot and ankle outcome score; GNM: goniometry; GRADE: grading of recommendations, assessment, development, and evaluations; HILT: High Intensity Laser Therapy (HILT); JFLS-20: jaw functional limitation scale-20; KSCRS: knee society clinical rating system; LBP: low back pain; LLLT: low-level laser therapy; MD: mean difference; MODQ: modified Oswestry disability questionnaire; NDI: neck disability index; NP: neck pain; NPRS: numeric pain rating scale; NR: not reported; ODI: Oswestry disability index; PDI: pain disability index; PI: pain intensity; PT: physical therapy; QoL: quality of life; RCTs: randomized controlled trials; RMQ: Roland Morris disability questionnaire; ROM: range of movement; SF-36: 36-item short form health survey; SMD: standardized mean difference; SPADI: shoulder pain and disability index; TE: therapeutic exercises; vs: versus; VAS: visual analogue scale; WOMAC: Western Ontario and McMaster Universities Arthritis Index  
The heterogeneity depends on the  $I^2$  statistic (>40%)

#### Appendix 1b. Umbrella Review of Systematic Reviews

Study	Results (95% CI)	Heterogeneity ( $I^2$ )	Quality of Evidence (GRADE)
Wyszyńska et al. (2018)	No meta-analysis was performed	NR	NR
Song et al. (2018)	MD: -0.91 cm (-1.2 to -0.6; $p < .01$ )	0%	NR
	MD: -1.02 cm (-1.5 to -0.6; $p < .01$ )	73%	NR
	MD: -1.16 cm (-2.9 to -0.6; $p = .2$ )	88%	NR
	MD: -0.82 cm (-1.4 to -0.2; $p < .01$ )	0%	NR
	MD: -1.01 cm (-1.3 to -0.7; $p < .01$ )	55%	NR
	SMD: -1.2 (-1.6 to -0.9; $p < .01$ )	2%	NR
	SMD: -1.9 (-3.6 to -0.2; $p = .03$ )	97%	NR
	SMD: -0.47 (-0.9 to -0.1; $p = .02$ )	0%	NR
	SMD: -0.32 (-0.2 to 0.5; $p = .45$ )	82%	NR

	SMD: -1.09 (-1.8 to -0.4; p<.01)	72%	NR
Alayat et al. (2019)	SMD: -0.83 (-1.4 to -0.3; p<.01)	NR	very low
	SMD: -1.22 (-1.6 to -0.9; p<.01)	0%	low
	SMD: -1.11 (-1.4 to -0.8; p<.01)	0%	NR
	SMD: -0.94 (-1.5 to -0.4; p<.01)	NR	very low
	SMD: -1.06 (-1.5 to -0.7; p<.01)	16%	low
	SMD: -1.03 (-1.3 to -0.7; p<.01)	0%	NR
	SMD: -1.10 (-1.9 to -0.3; p<.01)	NR	low
	SMD: -1.08 (-1.65 to -0.5; p<.01)	81%	very low
	SMD: -1.08 (-1.5 to -0.7; p<.01)	0%	NR
	SMD: -1.13 (-1.0 to -0.4; p<.01)	NR	low
	SMD: -3.56 (-4.0 to -3.1; p<.01)	NR	very low
	SMD: -2.37 (-4.8 to 0.0; p=.05)	96%	NR
	SMD: -1.65 (-2.4 to 0.9; p<.01)	80%	very low
	SMD: -1.17 (-1.5 to 0.9; p<.01)	0%	very low
Song et al. (2020)	MD: -1.18 cm (-1.7 to -0.7; p<.01)	90%	NR
	SMD: -1.17 (-1.5 to -0.9; p<.01)	0%	NR
	SMD: -5.36 (-7.4 to -3.3; p<.01)	90%	NR
Ezzati et al. (2020)	NR	NR	NR
de la Barra et al. (2021)	NR	NR	NR
Stasinopoulos et al. (2021)	NR	NR	NR
de la Barra et al. (2022)	MD: -1.23 cm (2.7 to -0.2; p=.10)	97%	NR
	MD: -1.90 cm (-2.6 to -1.2; p<.01)	68%	very low
	MD: 3.22° (-4.4 to 10.9; p=.41)	92%	NR
	MD: 5.02° (0.5 to 9.5; p=.03)	87%	NR
	MD: 4.19° (-5.4 to 12.9; p=.35)	95%	NR
	MD: 2.89° (-1.8 to 7.6; p=.35)	86%	NR
	MD: 5.26° (-3.0 to 13.5; p=.21)	94%	NR
	MD: 4.94° (-2.7 to 12.6; p=.20)	93%	NR
Starzec-Proserpio et al. (2022) (1)	No meta-analysis was performed	NR	moderate
	No meta-analysis was performed	NR	moderate
Wu et al. (2022)	MD: -0.81 cm (-0.4 to -1.2; p<.01)	46%	NR
	MD: -1.66 cm (-1.5 to -1.8; p<.01)	0%	NR
	MD: 6.48 points (4.1 to 8.9; p<.01)	0%	NR
	MD: 2.74 points (2.4 to 3.1; p<.01)	0%	NR
	MD: 0.78 points (0.5 to 1.0; p<.01)	0%	NR
	MD: 8.37 points (6.9 to 9.9; p<.01)	53%	NR
	MD: 10.9 points (8.9 to 12.9; p<.01)	65%	NR

Xie et al. (2023) (15)	SMD:2.12 (1.2 to 3.0; p<.05)	85%	moderate
	SMD:1.31 (0.3 to 2.4; p<.05)	92%	moderate
	SMD:1.43 (0.2 to 2.6; p<.05)	93%	moderate
	SMD:1.36 (0.2 to 2.6; p<.05)	92%	low
	SMD:1.04 (-0.2 to 2.3; p=.10)	93%	low
	SMD:1.45 (-0.2 to 3.1; p=.09)	96%	low
	SMD:0.96 (-0.2 to 2.1; p=.11)	92%	low
	SMD:0.96 (-0.8 to 1.7; p<.01)	91%	low
	SMD:1.73 (1.6 to 2.1; p=.06)	96%	low
	No meta-analysis was performed	NR	very low
Silva et al. (2023)	No meta-analysis was performed	NR	NR
Cai et al. (2023) (16)	MD:-2.04 cm (-2.1 to -2.0; p<.01)	93%	NR
	MD:-0.98 cm (-1.2 to -0.8; p<.01)	93%	NR
	MD:-1.54 cm (-1.8 to -1.2; p<.01)	83%	NR
	MD:-1.89 cm (-2.0 to -1.8; p<.01)	95%	NR
Arroyo- Fernández et al. (2023)	MD:-1.87 cm (-2.3 to -1.5; p<.01)	86%	low
	MD:-0.73 cm (-1.1 to -0.4; p<.01)	87%	NR
	MD:-1.28 cm (-1.6 to -1.0; p<.01)	89%	NR
	SMD:-1.46 (-2.0 to -0.9; p<.01)	92%	moderate
	SMD:-0.66 (-1.1 to -0.2; p<.01)	93%	NR
	SMD:-1.04 (1.1 to 0.7; p<.01)	92%	NR
	SMD=1.71 (1.1 to 2.4; p<.01)	92%	NR
	SMD: 0.21 (-0.7 to 1.1; p=.06)	94%	NR
	SMD:1.14 (0.6 to 1.7; p<.01)	93%	NR
	MD: 2.47 (-1.4 to 6.3; p=.21)	56%	NR
	MD:2.41 (-0.4 to 5.2; p=.09)	4%	NR
	MD:2.01 (-0.3 to 4.4; p=.09)	0%	NR
	MD:9.80 (5.7 to 13.9; p<.01)	23%	NR
	MD:10.16 (5.9 to 14.4; p<.01)	0%	NR
	MD:8.30 (4.8 to 11.8; p<.01)	83%	NR
	MD:7.17 (3.8 to 10.6; p<.01)	74%	NR
	MD:1.71 (-1.2 to 4.6; p=.24)	61%	NR
	MD:3.88 (0.5 to 7.3; p=.03)	73%	NR
	MD:9.72 (4.7 to 15.0; p<.01)	0%	NR
	MD:1.46 (-1.7 to 4.6; p=.36)	38%	NR
de la Barra et al. (2023) (17)	MD:-2.23 cm (-3.3 to -1.2; p<.01)	70%	low
	MD:-1.43 cm (-3.4 to 0.5; p=.15)	89%	NR
	MD:8.98° (-2.4 to 20.3; p=.12)	74%	low
	MD:-0.23° (-5.3 to 3.5; p=.67)	0%	low
	MD:3.44° (-6.9 to 13.7; p=.51)	64%	low
	MD:-10.08% (-16.5 to -3.7; p<.01)	0%	high

de la Barra et al. (2023) (17)	MD: -0.70 cm (-1.1 to -0.3; p<.01)	90%	very low
	MD: -1.27 cm (-1.9 to -0.7; p<.01)	47%	moderate
	MD: 0.39 cm (-0.25 to -1.0; p=.23)	0%	NR
	MD: -0.69 cm (-1.4 to 0.0; p=.06)	49%	NR
	MD: 0.58 cm (0.0 to 1.2; p=.06)	70%	NR
	MD: 5.93% (2.4 to 9.5; p<.01)	70%	low
	MD: 4.10% (-0.7 to 8.9; p=.10)	0%	NR
	MD: 4.91% (-0.3 to 10.2; p=.07)	0%	NR
	MD: 0.58% (-6.0 to 7.1; p=.86)	82%	NR
	MD: 14.42% (=9.4 to 19.4; p<.01)	90%	low
ElMeligie et al. (2023)	MD: -0.98 cm (-1.9 to -0.1; p<.01)	0%	low
	MD: -0.98 cm (-1.6 to -0.4; p<.01)	35%	NR
	MD: -0.98 cm (-1.5 to -0.5; p<.01)	0%	NR
	MD: 2.72 (-0.5 to 6.0; p=.10)	0%	NR
	MD: 0.47 (-4.0 to 3.1; p=.79)	0%	NR
Abdildin et al. (2023)	MD: -1.25 cm (-1.7 to -0.9; p<.01)	0%	high
	MD: -1.94 cm (-2.9 to -1.0; p<.01)	76%	NR
	MD: -1.65 cm (-2.2 to -1.1; p<.01)	43%	NR
	SMD: -0.67 (-1.2 to 0.1; p=.51)	73%	moderate
	MD: -1.36 points (-1.8 to -1.0; p<.01)	0%	high
	MD: -0.67 points (-1.2 to -0.1; p<.01)	73%	NR
Tang et al. (2023)	MD: -0.65 cm (-1.0 to -0.3; p<.001)	35%	very low
	SMD: 0.22 (-0.0 to 0.5; p=.082)	0%	very low
	SMD: 0.25 (-0.6 to 0.1; p=.129)	0%	very low
	SMD: -0.22 (-0.1 to 0.5; p=.138)	12%	NR
de la Barra et al. (2024) (18)	MD: -1.45 cm (-1.8 to -1.0; p<.001)	93%	low
	MD: -1.64 cm (-2.1 to -0.1; p<.001)	0%	very low
	MD: -1.21 cm (-2.0 to -0.4; p<.001)	83%	NR
	MD: -0.85 cm (-1.3 to -0.4; p<.001)	99%	low
	MD: -1.26° (-10.6 to 8.1; p=.79)	99%	NR
	MD: 3.93° (1.6 to 6.3; p<.001)	93%	low
	MD: 2.63° (1.2 to 4.0; p<.001)	89%	low
	MD: 3.19° (1.4 to 4.9; p<.001)	89%	low
	MD: 3.47° (1.3 to 6.6; p<.001)	93%	low
	MD: 3.73° (0.7 to 4.8; p<.001)	77%	low

Adapted from De la Barra et al. (2024), Lasers in Medical Science (2024) 39:290. (3)

CI: confidence interval; cm: centimeter; CPT: conventional physical therapy; DASH: the disabilities of the arm, shoulder and hand questionnaire; DNM: dynamometry; FAOS: foot and ankle outcome score; GNM: goniometry; GRADE: grading of recommendations, assessment, development, and evaluations; JFLS-20: jaw functional limitation scale-20; KSCRS: knee society clinical rating system; LBP: low back pain; LLLT: low-level laser therapy; MD: mean difference; MODQ: modified Oswestry disability questionnaire; NDI: neck disability index; NP: neck pain; NPRS: numeric pain rating scale; NR: not reported; ODI: Oswestry disability index; PDI: pain disability index; PI: pain intensity; QoL: quality of life; RCTs:



randomized controlled trials; RMQ: Roland Morris disability questionnaire; ROM: range of movement; SF-36: 36-item short form health survey; SMD: standardized mean difference; SPADI: shoulder pain and disability index; VAS: visual analogue scale; WOMAC: Western Ontario and McMaster Universities Arthritis Index

The heterogeneity depends on the I<sup>2</sup> statistic (>40%)