PHP_2.01.108	High Intensity Laser Therapy for Chronic Musculoskeletal Pain Conditions and Bell's Palsy		
Original Policy Date:	December 1, 2025	**Effective Date:**	June 1, 2026
Section:	2.0 Medicine	**Page:**	Page 1 of 21

State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

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**.

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.

Summary of Evidence

For individuals who have chronic musculoskeletal pain who receive HILT, the evidence includes randomized clinical trials (RCT) 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.

Additional Information
Not applicable.

Related Policies

- Low Level Laser Therapy

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

Regulatory Status

Examples of lasers that have been cleared for marketing by the 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]

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

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.[1]

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 1 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 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 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 500 mW and are classified as Class IV lasers by the 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
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 (MSP) 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 systematic reviews 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 1.

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 quality of life, 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 quality of life 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, quality of life, 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 (Starzec-Proserpio et al., 2022) and was included in the umbrella review (see Appendix 1).

Neck Pain

Three systematic reviews 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 1).

Knee Osteoarthritis

Khalilizad, 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 exercise therapy, and placebo with exercise therapy 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 analog 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 (Cai et al., 2023) and was included in the umbrella review (see Appendix 1).

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 (de la Barra Ortiz et al., 2023) and was included in the umbrella review (see Appendix 1).

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 quality of life 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, quality of life (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 visual analog scale (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 systematic reviews 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 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 2 and 3). 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 2. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
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.

[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 3. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Yilmaz et al (2022)[8]	1. Significant differences between groups at baseline suggests randomization was inadequate 3. No information on allocation concealment method			2. No intention to treat analysis.		
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.
[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 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)[12] identified only 1 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, 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 ($p<.001$) 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.

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 United States of America professional society, an international society with U.S. 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:[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

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 4.

Table 4. 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
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.

Appendix 1

Umbrella Review of Systematic Reviews

Table 1: Summary of Meta-analysis Results Reported by Systematic Reviews for HILT After Treatment

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)	Results (95% CI)	Heterogeneity (I2)	Quality of Evidence (GRADE)
Wyszyńska et al (2018)	NR	NR	NR	NR	NR	No meta-analysis was performed	NR	NR
Song et al (2018)	PI at rest (VAS) for back disorders	3	75	70	145	MD:−0.91 cm (−1.2 to −0.6; p<.01)	0%	NR
	PI at rest (VAS) for neck disorders	3	154	155	309	MD:−1.02 cm (−1.5 to −0.6; p<.01)	73%	NR
	PI at rest (VAS) for shoulder	2	68	68	136	MD:−1.16 cm (−2.9 to −0.6; p=.2)	88%	NR
	PI at rest (VAS) for arm/hand	3	71	75	146	MD:−0.82 cm (−1.4 to −0.2; p<.01)	0%	NR
	PI (VAS) overall	11	368	368	736	MD:−1.01 cm (−1.3 to −0.7; p<.01)	55%	NR
	Back disability	3	75	70	145	SMD:−1.2 (−1.6 to −0.9; p<.01)	2%	NR
	Neck disability	3	154	155	309	SMD:−1.9 (−3.6 to −0.2; p=.03)	97%	NR
	Shoulder disability	2	68	68	136	SMD:−0.47 (−0.9 to −0.1; p=.02)	0%	NR
	Arm/hand disability	2	71	75	146	SMD:−0.32 (−0.2 to 0.5; p=.45)	82%	NR
	Overall disability	10	344	344	688	SMD:−1.09 (−1.8 to −0.4; p<.01)	72%	NR
Alayat et al (2019)	HILT plus exercise in LBP	1	28	24	52	SMD:−0.83 (−1.4 to −0.3; p<.01)	NR	very low
	HILT plus exercise in NP	2	68	67	135	SMD:−1.22 (−1.6 to −0.9; p<.01)	0%	low
	HILT plus exercise for PI in spinal disorders overall	3	96	91	187	SMD:−1.11 (−1.4 to −0.8; p<.01)	0%	NR
	HILT plus exercise for disability in LBP	1	28	24	52	SMD:−0.94 (−1.5 to −0.4; p<.01)	NR	very low
	HILT plus exercise for disability in NP	2	68	67	135	SMD:−1.06 (−1.5 to −0.7; p<.01)	16%	low

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)	Results (95% CI)	Heterogeneity (I2)	Quality of Evidence (GRADE)
	HILT plus exercise for disability in spinal disorders overall	3	96	91	187	SMD−1.03 (−1.3 to −0.7; p<.01)	0%	NR
	HILT in LBP	1	15	15	30	SMD−1.10 (−1.9 to −0.3; p<.01)	NR	low
	HILT in NP	2	68	67	135	SMD:−1.08 (−1.65 to −0.5; p<.01)	81%	very low
	HILT for PI in spinal disorders overall	2	96	91	187	SMD:−1.08 (−1.5 to −0.7; p<.01)	0%	NR
	HILT for disability in LBP	1	15	15	30	SMD:−1.13 (−1.0 to −0.4; p<.01)	NR	low
	HILT for disability in NP	1	88	88	176	SMD:−3.56 (−4.0 to −3.1; p<.01)	NR	very low
	HILT for disability in spinal disorders overall	2	102	103	205	SMD:−2.37 (−4.8 to 0.0; p=.05)	96%	NR
	HILT plus PT in LBP	4	98	89	187	SMD:−1.65 (−2.4 to 0.9; p<.01)	80%	very low
	HILT plus PT for disability in LBP	4	98	89	187	SMD:−1.17 (−1.5 to 0.9; p<.01)	0%	very low
Song et al (2020)	PI (VAS)	6	182	152	334	MD:−1.18 cm (−1.7 to −0.7; p<.01)	90%	NR
	Stiffness (WOMAC and KSCRS)	4	87	81	168	SMD:−1.17 (−1.5 to−0.9; p<.01)	0%	NR
	Disability/function (WOMAC and KSCRS)	4	87	81	168	SMD:−5.36 (−7.4 to −3.3; p<.01)	90%	NR
Ezzati et al (2020)	NR	NR	NR	NR	NR	NR	NR	NR
De la Barra et al (2021)	NR	NR	NR	NR	NR	NR	NR	NR
Stasinopoulos et al (2021)	NR	NR	NR	NR	NR	NR	NR	NR
De la Barra et al (2022)	PI at rest (VAS)	3	86	86	172	MD:−1.23 cm (2.7 to −0.2; p=.10)	97%	NR
	PI at rest for 1-month follow-up (VAS)	2	61	61	122	MD:−1.90 cm (−2.6 to −1.2; p<.01)	68%	very low
	Cervical flexion (GNM)	2	61	61	122	MD:3.22° (−4.4 to 10.9; p=.41)	92%	NR
	Cervical extension (GNM)	2	61	61	122	MD:5.02° (0.5 to 9.5; p=.03)	87%	NR

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)	Results (95% CI)	Heterogeneity (I2)	Quality of Evidence (GRADE)
	Cervical right-side bending (GNM)	2	61	61	122	MD: 4.19° (−5.4 to 12.9; p=.35)	95%	NR
	Cervical left-side bending (GNM)	2	61	61	122	MD:2.89° (−1.8 to 7.6; p=.35)	86%	NR
	Cervical right rotation (GNM)	2	61	61	122	MD:5.26° (−3.0 to 13.5; p=.21)	94%	NR
	Cervical left rotation (GNM)	2	61	61	122	MD:4.94° (−2.7 to 12.6; p=.20)	93%	NR
Starzec-Proserpio et al (2022) [1]	PI (VAS, NPRS)	13	NR	NR	NR	No meta-analysis was performed	NR	moderate
	Function/disability (ODI, MODQ, RMQ, PDI, NDI, JFLS-20)	13	NR	NR	NR	No meta-analysis was performed	NR	moderate
Wu et al (2022)	PI (VAS) HILT vs LLLT	3	65	67	132	MD:−0.81 cm (−0.4 to −1.2; p<.01)	46%	NR
	PI (VAS) HILT vs placebo (both with exercise)	7	167	164	331	MD:−1.66 cm (−1.5 to −1.8; p<.01)	0%	NR
	Function (WOMAC) HILT vs LLLT	2	35	33	68	MD:6.48 points (4.1 to 8.9; p<.01)	0%	NR
	PI (WOMAC) HILT vs placebo (both with exercise)	4	87	81	168	MD:2.74 points (2.4 to 3.1; p<.01)	0%	NR
	Stiffness (WOMAC) HILT vs placebo (both with exercise)	4	87	81	168	MD:0.78 points (0.5 to 1.0; p<.01)	0%	NR
	Function (WOMAC) HILT vs placebo (both with exercise)	4	87	81	168	MD: 8.37 points (6.9 to 9.9; p<.01)	53%	NR
	WOMAC overall HILT vs placebo (both with exercise)	5	102	96	198	MD:10.9 points (8.9 to 12.9; p<.01)	65%	NR
Xie et al (2023)[15]	PI: HILT placebo vs HILT	4	113	112	225	SMD:2.12 (1.2 to 3.0; p<.05)	85%	moderate
	Cervical flexion ROM: HILT placebo vs HILT	4	113	112	225	SMD:1.31 (0.3 to 2.4; p<.05)	92%	moderate
	Cervical extension ROM: HILT placebo vs HILT	4	113	112	225	SMD:1.43 (0.2 to 2.6; p<.05)	93%	moderate
	Right side bending ROM:	3	93	32	125	SMD:1.36 (0.2 to 2.6; p<.05)	92%	low

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)	Results (95% CI)	Heterogeneity (I2)	Quality of Evidence (GRADE)
	HILT placebo vs HILT							
	Left side bending ROM: HILT placebo vs HILT	3	93	32	125	SMD:1.04 (−0.2 to 2.3; p=.10)	93%	low
	Right rotation ROM: HILT placebo vs HILT	3	93	32	125	SMD:1.45 (−0.2 to 3.1; p=.09)	96%	low
	Left rotation ROM: HILT placebo vs HILT	3	93	32	125	SMD:0.96 (−0.2 to 2.1; p=.11)	92%	low
	Cervical ROM overall: HILT placebo vs HILT	12	598	592	1190	SMD:0.96 (−0.8 to 1.7; p<.01)	91%	low
	Functional activity: HILT placebo vs HILT	3	83	83	166	SMD:1.73 (1.6 to 2.1; p=.06)	96%	low
	QoL: HILT placebo vs HILT	NR	NR	NR	NR	No meta-analysis was performed	NR	very low
Silva et al (2023)	NR	NR	NR	NR	NR	No meta-analysis was performed	NR	NR
Cai et al (2023)[16]	PI after treatment (VAS): HILT vs LLLT	2	69	67	136	MD:−2.04 cm (−2.1 to −2.0; p<.01)	93%	NR
	PI after treatment (VAS): HILT vs CPT	4	80	80	160	MD:−0.98 cm (−1.2 to −0.8; p<.01)	93%	NR
	PI after treatment (VAS): HILT+TE vs LLLT+TE	3	67	60	127	MD:−1.54 cm (−1.8 to −1.2; p<.01)	83%	NR
	PI overall	8	212	207	419	MD:−1.89 cm (−2.0 to −1.8; p<.01)	95%	NR
Arroyo-Fernández et al (2023)	PI after treatment (VAS): HILT vs sham/control	28	537	514	1051	MD:−1.87 cm (−2.3 to −1.5; p<.01)	86%	low
	PI after treatment (VAS): HILT vs other intervention	29	752	842	1594	MD:−0.73 cm (−1.1 to −0.4; p<.01)	87%	NR
	PI after treatment (VAS) overall	67	1289	1456	2745	MD:−1.28 cm (−1.6 to −1.0; p<.01)	89%	NR
	Functionality after treatment (VAS): HILT vs sham/control	24	460	535	995	SMD:−1.46 (−2.0 to −0.9; p<.01)	92%	moderate
	Functionality after treatment: HILT vs other intervention	23	592	697	1289	SMD:−0.66 (−1.1 to −0.2; p<.01)	93%	NR

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)	Results (95% CI)	Heterogeneity (I2)	Quality of Evidence (GRADE)
	Functionality after treatment overall	47	1052	1323	2375	SMD:−1.04 (1.1 to 0.7; p<.01)	92%	NR
	ROM after treatment: HILT vs sham/control	15	331	384	715	SMD=1.71 (1.1 to 2.4; p<.01)	92%	NR
	ROM after treatment: HILT vs other intervention	9	165	242	407	SMD: 0.21 (−0.7 to 1.1; p=.06)	94%	NR
	ROM after treatment overall	24	496	626	1122	SMD:1.14 (0.6 to 1.7; p<.01)	93%	NR
	Strength after treatment: HILT vs sham/control	4	80	87	167	MD: 2.47 (−1.4 to 6.3; p=.21)	56%	NR
	Strength after treatment: HILT vs other intervention	5	105	116	221	MD:2.41 (−0.4 to 5.2; p=.09)	4%	NR
	Strength after treatment overall	9	185	203	388	MD:2.01 (−0.3 to 4.4; p=.09)	0%	NR
	Physical functioning (SF-36)	6	117	140	257	MD:9.80 (5.7 to 13.9; p<.01)	23%	NR
	Role physical (SF-36)	6	117	140	257	MD:10.16 (5.9 to 14.4; p<.01)	0%	NR
	Bodily pain (SF-36)	6	117	140	257	MD:8.30 (4.8 to 11.8; p<.01)	83%	NR
	General health (SF-36)	6	117	140	257	MD:7.17 (3.8 to 10.6; p<.01)	74%	NR
	Vitality (SF-36)	6	117	140	257	MD:1.71 (−1.2 to 4.6; p=.24)	61%	NR
	Social functioning (SF-36)	6	117	140	257	MD:3.88 (0.5 to 7.3; p=.03)	73%	NR
	Role emotional (SF-36)	6	117	140	257	MD:9.72 (4.7 to 15.0; p<.01)	0%	NR
	Mental health (SF-36)	6	117	140	257	MD:1.46 (−1.7 to 4.6; p=.36)	38%	NR
De la Barra et al (2023)[17]	PI at rest (VAS)	5	109	118	227	MD:−2.23 cm (−3.3 to −1.2; p<.01)	70%	low
	PI at rest for 3-month follow-up (VAS)	4	74	83	157	MD:−1.43 cm (−3.4 to 0.5; p=.15)	89%	NR
	Shoulder flexion (GNM)	4	94	103	197	MD:8.98° (−2.4 to 20.3; p=.12)	74%	low
	Shoulder external rotation (GNM)	4	9	103	197	MD:−0.23° (−5.3 to 3.5; p=.67)	0%	low
	Shoulder abduction (GNM)	3	61	70	131	MD:3.44° (−6.9 to 13.7; p=.51)	64%	low

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)	Results (95% CI)	Heterogeneity (I2)	Quality of Evidence (GRADE)
	Shoulder disability (SPADI)	3	74	83	157	MD:−10.08% (−16.5 to −3.7; p<.01)	0%	high
De la Barra et al (2023)[17]	PI at rest (VAS)	6	168	168	336	MD:−0.70 cm (−1.1 to −0.3; p<.01)	90%	very low
	PI at first steps (VAS)	3	92	94	186	MD:−1.27 cm (−1.9 to −0.7; p<.01)	47%	moderate
	PI after walking (VAS)	2	76	78	154	MD:0.39 cm (−0.25 to −1.0; p=.23)	0%	NR
	PI at sitting (VAS)	2	76	78	154	MD:−0.69 cm (−1.4 to 0.0; p=.06)	49%	NR
	PI at rest for 3-month follow-up (VAS)	4	86	86	172	MD:0.58 cm (0.0 to 1.2; p=.06)	70%	NR
	PI at rest (FAOS subscale)	3	81	83	164	MD:5.93% (2.4 to 9.5; p<.01)	70%	low
	Daily life activities (FAOS subscale)	3	81	83	164	MD:4.10% (−0.7 to 8.9; p=.10)	0%	NR
	Symptoms (FAOS subscale)	3	81	83	164	MD:4.91% (−0.3 to 10.2; p=.07)	0%	NR
	Performance of sports & recreation activities (FAOS subscale)	3	96	98	194	MD:0.58% (−6.0 to 7.1; p=.86)	82%	NR
	Quality of life (FAOS subscale)	3	81	83	164	MD:14.42% (=9.4 to 19.4; p<.01)	90%	low
ElMeligie et al (2023)	PI at rest (VAS)	3	138	144	282	MD:−0.98 cm (−1.9 to −0.1; p<.01)	0%	low
	PI during activities (VAS)	5	94	99	193	MD:−0.98 cm (−1.6 to −0.4; p<.01)	35%	NR
	PI (VAS) overall	8	232	243	475	MD:−0.98 cm (−1.5 to −0.5; p<.01)	0%	NR
	Handgrip strength (DNM)	5	138	144	282	MD:2.72 (−0.5 to 6.0; p=.10)	0%	NR
	Mental component of QoL	4	123	129	252	MD:0.47 (−4.0 to 3.1; p=.79)	0%	NR
Abdildin et al (2023)	PI at rest (VAS)	2	46	41	87	MD:−1.25 cm (−1.7 to −0.9; p<.01)	0%	high
	PI at rest (VAS) 3-month follow-up	3	66	61	127	MD:−1.94 cm (−2.9 to −1.0; p<.01)	76%	NR

Study	Outcome	Number of RCTs in the Meta-analysis	Experimental (n)	Control (n)	Total (N)	Results (95% CI)	Heterogeneity (I2)	Quality of Evidence (GRADE)
	PI (VAS) overall	5	112	102	214	MD:−1.65 cm (−2.2 to −1.1; p<.01)	43%	NR
	Disability (ODI) after treatment	5	46	41	87	SMD:−0.67 (−1.2 to 0.1; p=.51)	73%	moderate
	Disability (RMQ) after treatment	4	66	61	127	MD:−1.36 points (−1.8 to −1.0; p<.01)	0$	high
	Disability (ODI and RMQ) overall	9	112	102	214	MD:−0.67 points (−1.2 to −0.1; p<.01)	73%	NR
Tang et al (2023)	PI at rest (VAS)	3	150	155	305	MD:−0.65 cm (−1.0 to −0.3; p<.001)	35%	very low
	Handgrip strength (DNM)	5	120	124	244	SMD:0.22 (−0.0 to 0.5; p=.082)	0%	very low
	Disability (DASH)	3	75	79	154	SMD:0.25 (−0.6 to 0.1; p=.129)	0%	very low
	QoL (SF-36)	2	44	45	89	SMD:−0.22 (−0.1 to 0.5; p=.138)	12%	NR
De la Barra et al (2024)[18]	PI at rest (VAS)	17	566	540	1106	MD:−1.45 cm (−1.8 to −1.0; p<.001)	93%	low
	PI at movement (VAS)	2	68	67	135	MD:−1.64 cm (−2.1 to −0.1; p<.001)	0%	very low
	PI at rest (VAS) 3-month follow-up	3	154	155	309	MD:−1.21 cm (−2.0 to −0.4; p<.001)	83%	NR
	Disability (NDI)	12	397	404	801	MD:−0.85 cm (−1.3 to −0.4; p<.001)	99%	low
	Cervical flexion (GNM)	9	271	251	522	MD:−1.26° (−10.6 to 8.1; p=.79)	99%	NR
	Cervical extension (GNM)	9	271	251	522	MD:3.93° (1.6 to 6.3; p<.001)	93%	low
	Cervical right-side bending (GNM)	9	251	251	502	MD=2.63° (1.2 to 4.0; p<.001)	89%	low
	Cervical left-side bending (GNM)	9	251	251	502	MD:3.19° (1.4 to 4.9; p<.001)	89%	low
	Cervical right rotation (GNM)	8	209	209	418	MD:3.47° (1.3 to 6.6; p<.001)	93%	low
	Cervical left rotation (GNM)	8	209	209	418	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]

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; 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 I2 statistic (>40%)

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

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
12/01/2025	New policy.
06/01/2026	Administrative update. Definitions of Decision Determinations section updated.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status

Below is an excerpt of the language taken from California Children's Services Numbered Letter 05-1020.*

*Department of Healthcare Services Numbered Letter 05-1020. Accessed April 21, 2026, from https://www.dhcs.ca.gov/services/ccs/Documents/CCS-NL-05-1020-Experimental-and-Investigational-Services.pdf

Policy

A. The California Children's Services (CCS) Program and the Genetically Handicapped Persons Program (GHPP) will not provide coverage for experimental services unless specifically authorized by law.
B. The CCS Program and GHPP may provide coverage for an investigational service if:
    1. It is approved by the FDA under any Investigational New Drug (IND) Application; or
    2. It is authorized for use under the State of California's Right to Try Act; and
    3. Its use is consistent with its FDA-approved IND Application or the State of California's Right to Try Act;
C. Additional criteria that will be considered in the adjudication process include:
    1. Conventional therapy will not adequately treat the intended patient's condition;
    2. Conventional therapy will not prevent progressive disability or premature death;
    3. The provider of the proposed service has a record of safety and success with it or equivalent to that of other providers of the investigational services;
    4. Other criteria (e.g., cost and availability) may be considered in the adjudication of a given request in cases in which more than one investigational service is available;
    5. There is reasonable expectation that the investigational service will significantly prolong the patient's life or will maintain or restore a range of physical and social function suited to activities of daily living; and
    6. The service is not being performed as part of a research study protocol. For a beneficiary with cancer who participates in a clinical trial for cancer, California Health and Safety

Code (HSC) § 1370.6 requires that all routine patient care costs related to the clinical trial be covered if the beneficiary's CCS-paneled treating physician recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential to benefit the enrollee. The coverage does not include investigational services that have not been approved by the FDA and that are associated with the clinical trial.

Feedback

Blue Shield of California Promise Health Plan is 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 Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan 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 member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.