

# Considered Judgement Form

This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations.

**Meeting date: 14/10/2014**

**Topic: Low-level Laser Therapy on Musculoskeletal Pain**

## Background and Purpose:

Low-level laser therapy (LLLT) is a non-invasive light source treatment that uses red and near-infrared monochromatic light to treat soft tissue injuries without increasing skin temperature. It has been developed as a technology for pain management and has been in use for decades. Several proposals have been made to explain how LLLT might work in terms of pain reduction. These mechanisms include a reduction of inflammation, analgesic effect and peripheral nerve stimulation. Although the exact mechanism of action remains to be fully elucidated, it appears that LLLT has a wide range of effects at the molecular, cellular and tissue levels.

In 2000, ACC completed an evidence based review examining the effectiveness of LLLT in the management of a diverse range of musculoskeletal conditions. The results suggested that LLLT did not establish itself as an effective therapeutic tool at the time of the review.

In response to a funding request, the Evidence Based Healthcare Team was asked to re-assess the effectiveness and safety of LLLT for musculoskeletal pain relief. The purpose of this evidence based review is to update ACC's 2000 review based on available recent systematic reviews on LLLT in order to inform purchasing decisions.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency / Clinical impact	
<i>Comment here on the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible, any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand Population, and the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence. Comment on the clinical impact e.g. size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit.</i>	<b>Evidence level (SIGN)</b>
<p><b><u>Effectiveness</u></b></p> <p>Nine systematic reviews (SRs) of various methodological quality were identified. There were two SRs that were appraised as 1++, five as 1+, and two were considered as 1- level of evidence.</p> <p><b>Tendinopathy</b></p> <p>The most comprehensive SR (Tumilty et al., 2010) with low risk of bias reviewed 25 trials (n=1,023 participants) in the treatment of tendinopathy, including lateral elbow tendinopathy, shoulder tendinitis, Achilles tendinitis, supraspinatus tendinitis, de Quervain's tenosynovitis and conditions with various tendinopathies. Twelve trials showed positive effects and 13 were</p>	<b>1+</b>

<p>inconclusive or showed no effect. Ten good quality studies with positive effects used LLLT dose within the WALT<sup>1</sup> recommended range. The authors concluded that LLLT was potentially effective in treating tendinopathy using WALT recommended dosages, but the overall evidence was inconclusive.</p>	
<p>One well-conducted SR (Bjordal et al., 2008) evaluated LLLT in 12 RCTs for the treatment of lateral elbow tendinopathy (tennis elbow). Eight RCTs reported positive findings in favour of LLLT for at least one outcome measure, while four RCTs reported non-significant findings or results in favour of control group. Conflicting data and significant heterogeneity among RCTs were noted in the meta-analysis results. However, it seems that LLLT using a 904-nm wavelength applied directly over the tendon area may be effective in reducing pain.</p>	1+
<p>One poor quality SR (Chang, Wu, Yang, &amp; Jiang, 2010) compared the effectiveness of applying LLLT to tender points and acupuncture points in patients with lateral elbow tendinopathy using similar data to Bjordal et al. The results revealed that applying LLLT on tender points or myofascial trigger points (MTrPs) could effectively improve the effect size (ES) of pain reduction.</p>	1-
<p><b>Neck pain</b></p>	
<p>One well-conducted SR (Chow, Johnson, Lopes-Martins, &amp; Bjordal, 2009) assessed 16 RCTs including a total of 820 patients. The categorical data from two RCTs suggested that LLLT improves pain over a placebo for acute neck pain. Results (of categorical data) for five trials of chronic pain suggested a greater benefit. Eleven trials assessed pain intensity in patients with chronic neck pain and the pooled result showed a significant reduction compared with placebo. The data showed considerable clinical heterogeneity, including different wavelengths, doses, treatment times and duration, and application techniques.</p>	1++
<p>Another more recent good quality SR (Gross et al., 2013) and meta-regression included 17 studies and suggested that LLLT is superior to placebo when applied to chronic neck pain in terms of improving pain/disability/QoL/GPE at intermediate-term. As with Chow's SR, all of the studies had small sample sizes and few male subjects were included.</p>	1+
<p><b>Joint disorders</b></p>	
<p>One well-conducted 2003 SR (Bjordal, Couppé, Chow, Tunér, &amp; Ljunggren, 2003) reviewed 14 trials to examine the effect of LLLT versus control group in the treatment of joint disorders, including back, knee, finger and temporomandibular joint. Before the reviewing procedures, the authors proposed a range of power densities and doses for the most common joints according to successful laboratory trials. Three studies which used doses lower than the suggested dose range found no significant difference between laser group and placebo group. The results of the remaining 11 trials showed pain reduction also significantly in favour of the laser groups.</p>	1+
<p>One fair quality (Petrucci, Sgolastra, Gatto, Mattei, &amp; Monaco, 2011) and one poor quality SR (Melis, Di Giosia, &amp; Zawawi, 2012) focus on temporomandibular joint (TMJ) disorders. The included studies were all small RCTs with considerable clinical heterogeneity. There were conflicting conclusions for using LLLT in the treatment of TMJ disorders in these two SRs.</p>	1+ 1-
<p>One Cochrane review (Yousefi-Nooraie et al., 2008) assessed 7 small RCTs investigating the effects of LLLT in patients with non-specific low-back pain. Three trials showed positive effects and four showed no effect. The limited data lead the authors to conclude that there were</p>	1++

<sup>1</sup> World Association of Laser Therapy  
Accident Compensation Corporation

<p>insufficient data to support the clinical effectiveness of LLLT for low-back pain.</p> <p>There was some positive outcome suggesting that LLLT with the recommended dose range was effective in reducing pain from chronic joint disorders. However, conflicting evidence from three recent SRs do not allow the reviewers to form a final opinion on effectiveness of LLLT in management of pain from low-back pain and temporomandibular disorders.</p> <p><b><u>External Peer Review Comments:</u></b></p> <p><i>“LLLT is looked upon as an alternative modality and not part of mainstream medicine. Amongst Physiotherapists, LLLT along with any electrotherapy device is looked upon ineffective. This is more to do with fashionable trends rather than evidence, and the fact that clinical applications and regimes are ill defined. As ACC research team has discovered, when sampling clinical trials the evidence is often mixed; this is not unusual for a modality where a dose/response is important. In the USA and Europe the utilisation of this device is driven by Physicians rather than Physiotherapists; unfortunately, if one is to take the evidence from presentations at international conferences on Laser therapy/medicine. Much of what is practiced is empirical rather than scientific. It seems that this device often waved around like a magic wand, which detracts from the applications where there is some evidence of effect.”</i></p> <p><b><u>SAFETY</u></b></p> <p>Side effects were mentioned in five SRs, three of which stated that there were no side effects or adverse events reported in the included RCTs related to LLLT during treatment or follow-up. Two SRs looking at the effects of LLLT on neck pain reported some mild side effects, including tiredness, nausea, increased stiffness, headache and increased pain. In addition, both of them included one trial that reported a significant increase in tiredness in the LLLT group. Chow et al. [10] also mentioned that low level lasers might have the potential for eye damage. However, no reports of such an injury in human trials have been found.</p>	
<p><b>2. Cost</b></p> <p><i>Comment on any economic costs associated with this service, product or procedure</i></p>	
<p>The cost of an LLLT device for medical use on the world wide web is from US \$2000 and up to US \$ 30,000.</p> <p>Treatment costs vary depending on the dosage and the duration of the treatment. The cost of one treatment for pain relief is typically about NZ \$40 with an average of 10 treatments given.</p>	
<p><b>3. Equity, Maori Health, Pacific Health, Acceptability</b></p> <p><i>Comment on the extent to which the service, product or procedure reduces disparities in health status (equity of access, resources, health outcome), is consistent with the treaty of Waitangi and encourages Maori/ Pacific participation in providing and using service, product and procedures, and is consistent with values and expectations of New Zealanders.</i></p>	
<p>No equity issues were identified.</p>	
<p><b>4. Consistency with the intent of the IPRC Act</b></p> <p><i>Purchasing decisions made by ACC must be consistent with and reflect consideration of factors described in the IPRC Act, Schedule 1, clause 2(1 and 2) and these decisions must be defensible against this statutory requirement in respect of individual claimants.</i></p>	
<p><b>5. Possible Purchasing Options</b></p> <p><i>List the possible purchasing options.</i></p>	
<p>The options are:</p>	

1. Purchase.
2. Do not purchase
3. Purchase on a case by case basis on the decision of the Corporate Medical Advisor (or equivalent)

## 6. Evidence Statement

*Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.*

*Suggested evidence statement:*

There is conflicting evidence that LLLT is effective for treating pain in patients diagnosed with tendinopathy. However, positive outcomes are more likely to be associated with the use of WALT recommended doses.

There is low to moderate evidence that LLLT is effective in the treatment of acute and chronic neck pain.

There is insufficient evidence to support the use of LLLT in the pain management of joint disorders.

There are no significant safety concerns reported in the literature.

## 7. Purchasing Recommendations

*What recommendation(s) does the advisory group draw from this evidence?*

*'Strong' recommendations should be made where there is confidence that, for the vast majority of people, the intervention/action will do more good than harm (or more harm than good). The recommendation should be clearly directive and include 'should/should not' in the wording.*

*'Conditional' recommendations, should be made where the intervention/action will do more good than harm, for most patients, but may include caveats eg on the quality or size of the evidence base, or patient preferences. Conditional recommendations should include 'should be considered' in the wording.*

Low level laser therapy should not be purchased for patients with musculoskeletal disorders because its effectiveness has not been established.

**Strong**

*Briefly justify the strength of the recommendation*

Despite some positive outcome, there was evidence of publication bias, which would be likely to increase the pooled effect estimate in favour of LLLT. Based on small trials and different populations, LLLT doses and comparison groups, there are insufficient data to either support or refute the effectiveness of LLLT for the treatment of musculoskeletal pain. The dose of laser irradiation is crucial for the interpretation of the outcome of LLLT studies. However, it is not possible to make robust estimates of the optimal dose for a broad range of musculoskeletal conditions due to significant clinical heterogeneity. There is no direct evidence suggesting that LLLT is more effective than other treatments in terms of pain management, i.e. NSAIDs, exercise, acupuncture, ultrasound and therapeutic massage.

**SIGN Levels of evidence:**

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

## References

- Bjordal, J. M., Couppé, C., Chow, R. T., Tunér, J., & Ljunggren, E. A. (2003). A systematic review of low level laser therapy with location-specific doses for pain from chronic joint disorders. *Australian Journal of Physiotherapy*, 49(2), 107-116.
- Bjordal, J. M., Lopes-Martins, R. A., Joensen, J., Coupe, C., Ljunggren, A. E., Stergioulas, A., & Johnson, M. I. (2008). A systematic review with procedural assessments and meta-analysis of low level laser therapy in lateral elbow tendinopathy (tennis elbow). *BMC Musculoskeletal Disorders*, 9(1), 75.
- Chang, W.-D., Wu, J.-H., Yang, W.-J., & Jiang, J.-A. (2010). Therapeutic effects of low-level laser on lateral epicondylitis from differential interventions of Chinese-Western medicine: systematic review. *Photomedicine and laser surgery*, 28(3), 327-336.
- Chow, R. T., Johnson, M. I., Lopes-Martins, R. A., & Bjordal, J. M. (2009). Efficacy of low-level laser therapy in the management of neck pain: a systematic review and meta-analysis of randomised placebo or active-treatment controlled trials. *The Lancet*, 374(9705), 1897-1908.
- Gross, A. R., Dziengo, S., Boers, O., Goldsmith, C. H., Graham, N., Lilge, L., . . . White, R. (2013). Low Level Laser Therapy (LLLT) for Neck Pain: A Systematic Review and Meta-Regression. *The open orthopaedics journal*, 7, 396-419.
- Melis, M., Di Giosia, M., & Zawawi, K. H. (2012). Low level laser therapy for the treatment of temporomandibular disorders: a systematic review of the literature. *CRANIO®*, 30(4), 304-312.
- Petrucci, A., Sgolastra, F., Gatto, R., Mattei, A., & Monaco, A. (2011). Effectiveness of low-level laser therapy in temporomandibular disorders: a systematic review and meta-analysis. *Journal of orofacial pain*, 25(4), 298-307.
- Tumilty, S., Munn, J., McDonough, S., Hurley, D. A., Basford, J. R., & Baxter, G. D. (2010). Low level laser treatment of tendinopathy: a systematic review with meta-analysis. *Photomedicine and laser surgery*, 28(1), 3-16.
- Yousefi-Nooraie, R., Schonstein, E., Heidari, K., Rashidian, A., Pennick, V., Akbari-Kamrani, M., . . . Mortaz Hejri, S. (2008). Low level laser therapy for nonspecific low-back pain. *Cochrane Database Syst Rev*, 2.