


National Institute for Health and Care Excellence

IP1551 / Low-level laser therapy for preventing or treating oral mucositis caused by radiotherapy or chemotherapy

IPAC date: 8 March 2018

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Company Quintain Medical Ltd.	General	<p>Please find attached the response from Thor Photomedicine Ltd, on whose behalf I am acting, to the following:</p> <ol style="list-style-type: none"> 1. Interventional Procedure Consultation Document – IP 1551 2. Overview 3. Specialist Advice Questionnaires <p>Following on a separate email, due to attachment size limitations (3+mB), are the original SIR document and associated documents zip file, plus the two additional documents mentioned in the text of this email attachment.</p> <p>If you have any further questions, please contact me directly.</p> <p>Please can you respond to the receipt of this and the subsequent emails with an acknowledgement?</p> <p>Best Regards <div style="background-color: black; width: 100px; height: 15px; margin: 5px 0;"></div> Quintain Medical Ltd.</p>	<p>Please respond to all comments</p> <p>Thank you for your comments. The IP team has received and considered this information.</p>

2	Consultee 1 Company Quintain Medical Ltd.	General	<p>As per previous email, please find the following attachments:</p> <ol style="list-style-type: none"> 1. SIR 2. Zip File with associated documents 3. Two additional papers mentioned in the previous email <p>Best Regards </p> <p>How to Report Low-Level Laser Therapy (LLLT)- Photomedicine Dose and Beam Parameters in Clinical and Laboratory Studies.pdf</p> <p>SIR 1551 - THOR PhotoMedicine Ltd Final.docx</p> <p>The dark art of light measurement- accurate radiometry for low-level light therapy.pdf</p> <p>NICE IPP attachments.zip</p>	<p>Thank you for your comments.</p> <p>The Committee has received and considered this information.</p> <p>The first publication is a reference paper that sets the criteria for reporting LLLT parameters in clinical trials. The second paper is a systematic review assessing the appropriateness of LLLT parameters reported in the literature. The papers are not clinical studies and do not fulfil the criteria for inclusion in the synthesis of evidence.</p>
3	Consultee 1 Company Quintain Medical Ltd.	General	<p>Dear Sir/Madam,</p> <p>I am responding to the request for public consultation, on behalf of my client – Thor PhotoMedicine Ltd. This is additional relevant evidence, with references, as requested in the outline of the public consultation.</p> <p>Please find attached documents pertaining to the Low-level laser therapy for preventing or treating oral mucositis caused by radiotherapy or chemotherapy: Interventional procedure consultation (IP1551).</p>	<p>Thank you for your comments.</p> <p>The IP team has received and considered this information.</p>

			<p>This follows on from the previous SIR response from Thor, with associated reference documents.</p> <p>There are 5 attachments:</p> <ol style="list-style-type: none"> 1. Cover Document referencing <ol style="list-style-type: none"> a. 3 forms of NYU Dose Summary data b. A Reference paper <p>Please can you acknowledge receipt of this email?</p> <p>Best Regards ██████████ Quintain Medical Ltd.</p> <p>██████████ <u>Copy of NYU dose summary.xlsx</u> ██████████ <u>\FURTHER INFORMATION FROM THOR PHOTOMEDICINE FOR PUBLIC INPUT CONSIDERATION.docx</u> ██████████ <u>\NYU dose summary.pdf</u></p> <p>██████████ <u>\NYU dose summary copy.numbers</u> ██████████ <u>\The dark art of light measurement-accurate radiometry for low-level light therapy.pdf</u></p>	
4	Consultee 1 Company Quintain Medical Ltd.	Specialist advisers' opinions	<p>Are we permitted to suggest further clinicians here as there are only 2 questionnaires completed here: ██████████, Consultant H&N Oncologist from ██████████ and ██████████, a Consultant Oncologist from ██████████ ██████████?</p>	<p>Thank you for your comments. Before a procedure is considered by the Committee, NICE seeks the opinion of at least two Specialist Advisers who are nominated by relevant Specialist Societies</p>

			Further references – including some external to the UK – with extensive experience of LLLT in OM, are shown in Appendix 1 overleaf.	
5	Consultee 1 Company Quintain Medical Ltd.	Company engagement	<p>The last sentence is incorrect. [REDACTED], Quintain Medical Ltd. and on behalf of Thor Photomedicine Ltd., emailed the completed SIR form and attachments containing supporting documentation to [REDACTED]. The date my e-mail with attachments was sent was: 10th November 2017 at 15.21</p> <p>Sent it to: ipinformationrequest@nice.org.uk</p> <p>The initial e-mail came [REDACTED] [REDACTED]@nice.org.uk and was sent to [REDACTED] on 27th October 2017 at 15.23.</p> <p>When we appeared at the NICE IPAC panel meeting on the morning of 14th December 2017, at Borough High Street, we were informed that we were not registered to join the IPAC meeting and that the IPinformation request email ‘was no longer used’. This was strange as there was no ‘non-delivery message’ to the email – and if it was received and had been marked in the Subject line as ‘For the attention of [REDACTED]’; why was it not passed on?</p> <p>A complete copy of the email is shown overleaf in Appendix 2. A copy of the completed SIR plus zip</p>	<p>Thank you for your comments.</p> <p>The IP team has received and considered the structured information provided by the company at the time of preparing the overview but this was not included in the Company engagement statement due to a technical error.</p> <p>The Committee has decided to change the wording in the company engagement statement to:</p> <p>“A structured information request was sent to 2 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview”</p>

			file of attachments is being sent by separate email – for the record.	
6	Consultee 1 Company Quintain Medical Ltd.	Draft recommendations	We welcome this. Thor Photomedicine has highlighted that variation in parameters and dose is significant in PBMT (PhotoBioModulation Therapy [LLLT]) studies generally, making it very difficult to compare. Following on from the LiTEFORM trial, our aim is a trial to look at dose and parameters in PBMT for HNC RCT OM.....which would be a hugely important next contribution in advocating this procedure. I attach 2 papers on this very issue with the follow on email with the references provided in the original email.	Thank you for your comment. The consultee agrees with main recommendation. The first publication is a reference paper that sets the criteria for reporting LLLT parameters in clinical trials. The second paper is a systematic review assessing the appropriateness of LLLT parameters reported in the literature. The papers are not clinical studies and do not fulfil the criteria for inclusion in the synthesis of evidence.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."