




National Institute for Health and Care Excellence
IP1718 High-intensity focused ultrasound for symptomatic benign thyroid nodules

IPAC 13/12/18

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Consultant ENT Surgeon Specialist Advisor	3.6	<p>Only thing I would say is that the statement that</p> <p>The committee noted that the procedure is not an effective treatment for hyper-functioning nodules causing thyrotoxicosis.</p> <p>is not really supported in the literature with some good series showing successful treatment o toxic nodules</p>	<p>Thank you for your comment.</p> <p>Section 3.6 of the draft guidance has been changed as follows: <i>“ 3.7. The committee noted that there is little evidence for the use of the procedure in the treatment of thyrotoxicosis caused by hyper-functioning nodules. ”</i></p>
2	Consultee 2 Society for Endocrinology	2.2	<p>A member of our Clinical Committee disagrees with the statement in point 2.2 on page 3 “Conventional treatment includes levothyroxine to suppress thyroid-stimulating hormone (TSH)-stimulated growth of thyroid tissue”</p> <p>Levothyroxine to suppress serum TSH is NOT conventional treatment and goes against recommendations of all current guidelines on management of thyroid nodules. This is wrong and is in stark contrast with the recommendations that will be made in the NICE Guidance on Thyroid Diseases.</p>	<p>Thank you for your comment and for pointing out this inconsistency with the NICE clinical guideline on Thyroid Diseases that is currently in development.</p> <p>Section 2.2 of the guidance has been changed as follows: <i>“ Treatment of benign thyroid nodules may be needed if they cause symptoms or cosmetic problems.</i></p>

				<i>Conventional treatment includes surgery. Other less invasive approaches than surgery include ethanol ablation, percutaneous laser ablation, radiofrequency ablation and microwave ablation.”</i>
3	Consultee 2 Society for Endocrinology	General	<p>The Clinical Committee comment that:</p> <p>There is little evidence on HIFU. This may be of use although the evidence is poor at present. There are several issues:</p> <ol style="list-style-type: none"> 1. Time required to ablate - it’s a slow process associated with pain so realistically only small nodules are suitable and studies to date exclude malignancy. So is this useful if only small benign nodules can be ablated? 2. Studies have shown unpredictable outcomes – unsurprising as there is very limited evidence. 3. Max treatment depth is approximately 3cm deep to skin, limiting its use. 	<p>Thank you for your comment and for highlighting these 3 issues.</p> <p>The main recommendations say: <i>1.1 The evidence on the safety of high-intensity focused ultrasound for symptomatic benign thyroid nodules raises no major safety concerns, however the current evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.</i></p> <p>The consultee agrees with the main recommendations regarding the limited evidence.</p> <p>The committee considered your comment but decided not to change the guidance.</p>
4	Consultee 3 Company	3.6	Dear IPP team, we would like to bring to your attention that our HIFU technology has been CE marked for cold and hot nodules.	Thank you for your comment and for sending through these 3 publications.

	Theraclion	<p>The evaluation states: “The committee noted that the procedure is not an effective treatment for hyper-functioning nodules causing thyrotoxicosis.”</p> <p>There have been studies to show effectiveness also in hyperfunctioning nodules and it clearly is an indication in other countries, even reimbursed by 30 public insurance companies in Germany. There is a great benefit in avoiding the use of radioactive iodine for patients with hyperfunctioning nodules, or avoiding surgery. Many patients today are looking for non-ionizing radiation treatment and non-invasive treatment.</p> <p>We would like to ask you to consider this information and the attached publications for this sub-indication and revise the statement above if possible.</p> <p>Kind regards,</p> <p>[Redacted]</p> <p>[Redacted]</p> <p> IntJournalHyperthe rnia_Korkusuz_14Oç</p> <p> JournalTherapUltra sound_Korkusuz_30</p> <p> Esnault case report 2010.pdf</p>	<p>The first paper is the Esnault (2010) single case report that is included in the Appendix. It describes the first successful ablation of a toxic thyroid nodule with HIFU.</p> <p>The second paper is the Korkusuz (2014) study. It is a case series of 10 patients with a 1-day follow-up. It is also included in the Appendix. The conclusion says that: “ HIFU is a safe and effective method to treat benign, solid, complex, hot and cold thyroid nodules preserving thyroid function.”</p> <p>The third paper is another Korkusuz (2014) study that is also included in the Appendix and in the Lang 2017a systematic review that is included in Table 2. It is a case series of 10 patients including 4 hot or indifferent benign thyroid nodules. The conclusion says: “ HIFU appears to be safe and is an easy to perform means of thermal ablation.”</p> <p>Section 3.6 of the draft guidance has been changed as follows: <i>“ 3.7. The committee noted that there is little evidence for the use of the procedure in the treatment of thyrotoxicosis caused by hyper-functioning nodules.”</i></p>
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5	Consultee 4 The Royal College of Radiologists	1	Dear [REDACTED], Apologies for the delay in our response. We support this guidance, and it seems that this procedure is likely to be safer than the alternative forms of ablation (RF and microwave) as there is less damage to other structures. We hope you can still accept our comments. Many thanks, [REDACTED]	Thank you for your comment. The consultee agrees with the main recommendations.
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