

National Institute for Health and Care Excellence

IP1043 Transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain

IPAC 13/09/18

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 Company Insightec	1.1	<p>NICE is currently consulting on draft guidance for Transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain.</p> <p>To the best of our knowledge, no clinician in the UK is at present proposing to use the single Exablate Neuro currently installed in the UK to treat neuropathic pain outside a research ethics approved trial. As there is no other device in the UK capable of delivering transcranial MRI-guided focused ultrasound thalamotomy, unless NICE has information to the contrary, we draw to NICE's attention to §5.3 of the current version of the Interventional Procedures Programme Manual:</p> <p style="text-align: center;"><i>If a procedure notified to the programme appears to fall within the remit of the programme in all respects except that it is not yet being used in the NHS or independent healthcare sector, or there is no evidence base with which to assess it, the programme monitors it and assesses it at a future date if circumstances change. Such procedures are listed on NICE's website, along with the reason why they are not yet being assessed.</i></p> <p>We submit that the proposed guidance on transcranial MRI-guided focused ultrasound thalamotomy in the treatment of neuropathic pain should not be published, and the procedure be monitored (along with</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>When NICE sought the opinion of specialist advisers, we were told that there was interest in using this procedure in the UK to treat neuropathic pain. Furthermore, there is published evidence available and a device is CE marked for use in this indication.</p> <p>The Committee considered this comment but decided not to change the guidance.</p>

			<p>156 procedures previously notified to the committee, see https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance/ip-list)until NICE is notified of a wish to perform the procedure outside a research setting.</p> <p>In the event that NICE feels that it is necessary to proceed with issuing guidance on transcranial MRI-guided focused ultrasound thalamotomy despite the published process set out in §5.3 of the IP Programme Manual, we strongly suggest that the wording “Therefore, this procedure should not be used.” in §1.1 be revised to read “Therefore, this procedure should only be used in the context of research.:</p>	
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