

National Institute for Health and Care Excellence

IP1774 Transcervical ultrasound-guided radiofrequency ablation for symptomatic uterine fibroids

IPAC date: 14 January 2021

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	General	<p>Useful addition to options of management of uterine fibroids</p> <p>In [REDACTED] we carried out a number of cases, all under local anaesthetic and generally well tolerate by patients in an ambulatory setting.</p> <p>Procedure is best for intra-mural fibroids ranging between 2-6cm in size. Larger fibroids up to 8-9cm may be treated following a course of LHRHa to reduce size.</p> <p>For submucous fibroids hysteroscopic morcellation and/or resection is probably more appropriate</p> <p>For serous fibroids, laparoscopic or open surgical approach is more relevant.</p> <p>Larger intramural fibroids >10cm may need embolization or surgery (myomectomy or hysterectomy).</p>	Thank you for your comment.
2	Consultee 1 NHS Professional	General	<p>Main problem with this treatment will be tariff. The cost of the device is relatively high (about £3000)</p>	Thank you for your comment.

			excluding other cost for staffing, equipment, overheads etc.	Cost is not within the remit of the IP programme.
3	Consultee 2 Company Gynesonics	3.1	This section describes and classifies three of the studies reviewed by NICE as 'case series'. The Committee is asked to consider whether, in fact, two of these studies (SONATA and FAST-EU studies) are better described and classified as 'cohort studies'. Unlike case series, these studies both had prospectively defined endpoints with associated success criteria and defined inclusion/exclusion criteria. These studies also had defined follow-up time points. As cohort studies, these studies provide a higher quality level of evidence compared with the case series. These studies are described in more detail in the Overview document (Studies 1-5), where they are also described as case series, whereas describing them as cohort studies may be more appropriate.	Thank you for your comment. The guidance and overview have been changed to described the 2 studies as cohort studies.

"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."