### Advice Statement 001/2015

**December 2015**

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<th><strong>Is magnetic resonance guided focused ultrasound surgery (MRgFUS) for the treatment of uterine fibroids clinically effective, safe and cost effective compared with uterine artery embolisation (UAE), myomectomy and hysterectomy?</strong></th>
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This advice has been produced following completion of [evidence note 55](#) by Healthcare Improvement Scotland, in response to an enquiry from NHS National Services Scotland.

#### Background

MRgFUS is a non-invasive treatment for symptomatic uterine fibroids typically performed on an outpatient basis by an interventional radiologist. Currently there are two CE marked MRgFUS systems, namely Insightec's ExAblate 2000 system and upgraded ExAblate 2100 conformational system (Insightec) and Philips' Sonalleve (Philips Medical Systems). MRgFUS treatment for uterine fibroids is currently available in the United Kingdom (UK) in only one tertiary referral centre at St Mary's Hospital in London, which is equipped with the ExAblate 2100 system.

The cost of the ExAblate system in North America ranges from US$750,000 to US$1.5 million and approximately US$1 million for the Sonalleve system.

The St Mary's Hospital, London, is the single UK tertiary centre accepting referrals only from consultant gynaecologists across the UK and has no pre-defined patient pathway. NICE interventional procedure guidance (IPG) advises that patient selection should be carried out by a multidisciplinary team including a gynaecologist and an appropriate imaging specialist. Clinical and technical reasons limit the number of patients for whom the procedure would be suitable.

#### Clinical effectiveness

- There are currently no published randomised controlled trials (RCTs) comparing MRgFUS with alternative treatment options for symptomatic uterine fibroids.
- The quantity and quality of evidence is insufficient to determine whether or not MRgFUS is clinically effective compared with UAE, myomectomy or hysterectomy for the treatment of uterine fibroids.

#### Safety

- The NICE IPG concluded that there are well-recognised complications associated with MRgFUS but the evidence on safety was adequate to support the use of the procedure provided that normal arrangements are in place for clinical governance and audit.
- The guidance stated that during the consent process clinicians should inform patients...
about the risk of skin burns and that the effect on subsequent fertility and pregnancy was uncertain.

**Cost effectiveness**
- There are five cost effectiveness studies (one UK and four North American). The robustness of the results was compromised owing to an absence of head to head trial data, a large number of assumptions in the models, and the use of unpublished data. Overall, the available cost effectiveness evidence was conflicting and inconclusive and thus it was not possible to determine whether MRgFUS is cost effective compared with UAE, myomectomy or hysterectomy for the treatment of uterine fibroids.

**Context/conclusion**
- The identified evidence base does not support investment in MRgFUS for the treatment of uterine fibroids by NHSScotland at this time.
- There are two ongoing RCTs investigating the use of the ExAblate (comparator UAE) and Sonalleve (comparator sham MRgFUS) systems in the treatment of pre- or peri-menopausal women with symptomatic uterine fibroids.
- The National Specialist Services Committee for NHSScotland will use this Advice Statement to inform its deliberations on the establishment of a national MRgFUS service.

**Advice context:**
*The status of SHTG Advice Statements is ‘required to consider’.*

No part of this advice may be used without the whole of the advice being quoted in full. This advice represents the view of the SHTG at the date noted.

It is provided to inform NHS boards in Scotland when determining the place of health technologies for local use. The content of this Advice Statement was based upon the evidence and factors available at the time of publication. An international evidence base is reviewed and thus its generalisability to NHSScotland should be considered by those using this advice to plan services. It is acknowledged that the evidence constitutes only one of the sources needed for decision making and planning in NHSScotland. Readers are asked to consider that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. SHTG Advice Statements are considered for review on a 2-yearly basis. The evidence will be updated if requested by the clinical community, dependent on new published reports. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Chair
Scottish Health Technologies Group

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