

# High-intensity focused ultrasound for glaucoma

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg661](http://www.nice.org.uk/guidance/ipg661)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# 1 Recommendations

- 1.1 Evidence on the safety and efficacy of high-intensity focused ultrasound for glaucoma is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Research should ideally take the form of randomised controlled trials comparing this procedure with standard therapies and should report safety events and long-term outcomes.
- 1.3 NICE may update the guidance on publication of further evidence.

# 2 The condition, current treatments and procedure

## The condition

- 2.1 Glaucoma is usually a chronic condition associated with elevated intraocular pressure. The most common type of glaucoma in the UK is primary open-angle glaucoma, also known as chronic open-angle glaucoma. It leads to progressive damage to the optic nerve. Early stages are usually asymptomatic but as the condition progresses it causes visual impairment and, if untreated, blindness.

## Current treatments

- 2.2 [NICE's guideline on glaucoma](#) describes its diagnosis and management. Treatment is usually eye drops containing drugs that either reduce the production of aqueous humor (fluid) or increase its drainage. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy or laser trabeculoplasty may also be used.

## The procedure

- 2.3 This procedure uses high-intensity focused ultrasound (HIFU) to partially destroy the ciliary body to reduce the production of aqueous humor and thereby decrease the intraocular pressure.
- 2.4 The procedure can be done under regional, general or topical anaesthesia. One device available for this procedure consists of a compact operator console and a disposable probe (which includes a coupling cone and a therapy probe that generates the ultrasound beams). The coupling cone is placed directly on the centre of the patient's cornea and held in place by a low-vacuum suction ring. A ring-shaped therapy probe (connected to the console) that generates ultrasound beams is inserted into the cone. The space between the eye, cone and the probe is filled with saline solution to ensure dissemination of ultrasound energy. By pressing the foot switch, miniature transducers in the ring-shaped probe are sequentially activated to deliver HIFU beams directly into the ciliary body. These beams pass through the scleral tissue without disruption of ocular tissue to reach the ciliary body. The ultrasound heats and inactivates tissue within the ciliary body to decrease the production of aqueous humor.

## 3 Committee considerations

### The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature

search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 1 meta-analysis, 1 non-randomised comparative study and 7 case series (2 of which were also included in the meta-analysis). It is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, reduction in intraocular pressure, reduced use of medication and preservation of visual fields, in the long term.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: hypotony, pain and macular oedema.

## Committee comments

- 3.4 The committee noted that the technology is evolving.
- 3.5 The committee noted that in the context of such a common condition, there was a lack of controlled studies of sufficient statistical power, and this underpinned their recommendation for further research.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).