NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10090 Monofocal intraocular lenses for cataract surgery

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are monofocal intraocular lenses (IOLs) for cataract surgery. Guidance on these technologies will be developed using the existing-use approach. Existing-use assessments consider HealthTech products that are already in established use within the NHS, to inform commissioning and procurement decisions.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

Cataracts are very common. They affect around 1 in 3 people over the age of 65 in the UK. They are cloudy areas in the lens of the eye. Symptoms include blurred vision, difficulty seeing at night, reading, or watching television, sensitivity to light and glare, double vision (looking at 1 object but seeing 2), and colours looking faded. Without treatment cataracts may cause sight loss. Surgery is used to treat cataracts by replacing the cloudy natural lens with an IOL. Cataract surgery is the most common surgery in the NHS with around 681,400 publicly funded procedures performed in 2023.

3. Current practice

In the NHS, the referral, diagnosis and treatment of cataracts is informed by guidelines from both NICE and the Royal College of Ophthalmologists. The relevant guidelines are:

- NICE Cataract in adults: management guideline (NG77)
- Higher Flow Any Complexity Cataract Surgery (HFAC) guidance from the Royal College of Ophthalmologists, updated in September 2025.
- Sustainable cataract surgery from the Royal College of Ophthalmologists, updated in September 2025.
- Quality Standards for Cataract Services from the Royal College of Ophthalmologists, updated in September 2021.
- Quality Standards for Correct IOL implantation in cataract surgery from the Royal College of Ophthalmologists, updated in December 2021.
- Guideline for Cataract Surgery, from the European Society of Cataract and Refractive Surgeons (ESCRS), published in September 2025.

3.1 Intraocular lens selection for cataract surgery

People with cataracts usually present to an optician or GP when they notice gradual changes in their vision. People with cataracts are referred for surgery when their eyesight, quality of life, or ability to perform daily tasks (such as driving or reading) is significantly impaired.

When people are referred a preoperative assessment is carried out before the surgery and this includes biometry and intraocular lens (IOL) selection. A healthcare professional, usually a surgeon, makes the IOL selection based on a shared decision-making discussion with the patient. Patient-related factors include a person's lifestyle and visual goals; ocular health and anatomy, such as pupil size and axial length; and previous experience with cataract surgery if applicable. Factors related to the individual surgeon such as familiarity with specific IOL products, level of expertise, training background and access to products can also influence IOL selection (Kabbani et al., 2024).

3.2 Cataract surgery

Cataract surgery involves removing the clouded natural lens and replacing it with a clear artificial IOL. The surgery is performed in a hospital, almost always as an outpatient (day surgery) procedure. The operation is usually done under a local anaesthetic and takes between 20 minutes and 45 minutes to complete.

During cataract surgery, a phacoemulsification machine delivers ultrasonic energy to break up the clouded lens and remove it through a small incision. The monofocal IOL is usually placed in the capsular bag, a thin membrane which originally surrounded the natural lens. If this bag is damaged the surgeon may place a monofocal IOL in the ciliary sulcus (a small groove behind the iris) or attach it directly to the iris.

In terms of clinical outcomes, cataract surgery significantly improves visual acuity, improving quality of life, while reducing risks of falls, fractures, dementia, and depression. Around 95% of people without pre-existing ocular pathology achieve best-corrected visual acuity of 6/12 or better, which is the threshold required to meet UK driving standards.

3.3 Current NHS market for the technologies

Cataract surgery is the most common surgery in the NHS. Around 681,400 publicly funded procedures were performed in England between April 2023 and March 2024, at an estimated cost of over £750 million (RCOPHTH, 2025).

NHS funded cataract surgery is provided using a mix of both NHS treatment centres and independent sector treatment providers. The role of independent sector providers in conducting NHS-funded cataract surgery increased from less than 20% in 2016, to 59% by January 2024 (Maling and Adams, 2024).

For cataract surgery performed by NHS treatment centres, monofocal IOLs may be purchased through the NHS Supply Chain framework agreement. The current framework started on 3 November 2025 and runs for 24 months, with an option to extend for an additional 24 months. There are 12 suppliers on the Complete Ophthalmology Solutions 3 framework with 104 product ranges, of

which around 70% are standard monofocals. Recent estimates from NHS Supply Chain are that around 35-40% of IOL procurement goes through their framework, with the rest purchased independently by NHS Trusts.

Monofocal IOLs pricing varies according to both product features and purchasing volumes. For example, a large multicentre study including 907,052 publicly funded cataract operations from 87 UK centres reported a mean price of £45.72 for IOLs made from hydrophobic materials, compared with £42.86 for IOLs made from hydrophilic materials (Ting et al., 2023).

Lens costs for independent sector providers vary from those available to NHS supply chain. Many of the independent sector providers have arrangements with one lens company and use the same range of IOLs for all its procedures. Some NHS trusts also having purchasing arrangements with one lens company. Where lenses are purchased directly from suppliers, NHS trusts and private providers often have a purchase package which may include arrangements such as volume-based discounts, and amortisation of surgical equipment.

4. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions.

4.1 Purpose of the technologies

Monofocal IOLs are small artificial lenses implanted in the eye during cataract surgery. They replace the eye's cloudy natural lens to restore focus and vision after cataract removal. Monofocal IOLs are used for NHS-funded cataract surgery and are designed to correct vision to a single focus point. This means they can be optimised for either near or distance vision, with glasses needed for other ranges.

4.2 Basic technology requirements

Monofocal IOLs have evolved over time, with adjustments to several features resulting in a range of options. Basic requirements of all monofocal IOLs, regardless of features, include:

- Regulatory approval: IOLs must have appropriate CE or UKCA marking as medical devices.
- UV protection: ultraviolet light should be filtered out by the lens. This is intended to protect the retina from damage, as the natural lens, which previously blocked this light, has been removed.
- Biocompatibility: lens materials are required to be chemically inert, non-toxic, and non-immunogenic.
- Strict power tolerance: a lens labelled with a specific dioptre (D) must fall within narrow accuracy ranges to meet industry standards and ensure accuracy.
- Stability: lenses should maintain precise axial, rotational, and centration alignment to ensure optimal vision after implantation.
- Sterile: IOLs must comply with CE/UKCA marking standards for sterility.

4.3 Types of monofocal intraocular lens

The NHS offers monofocal IOLs for cataract surgery. The NHS Supply Chain framework includes 4 categories of monofocal IOLs. These are standard, which correct vision for a single fixed focus (usually distance); enhanced monofocal (also known as monofocal plus), which correct vision for a single focus and offer a moderate improvement in visual range (into the intermediate range); toric monofocal, which correct astigmatism with a single fixed focus; and toric enhanced, which correct vision like toric IOLs and offer a moderate improvement in visual range.

Many of the features of the IOLs are associated with lens design choices to try to optimise the person's vision. During surgery most IOLs will be placed within the capsular bag. However for some people this may not be possible and the IOL is located outside the bag. Monofocal IOLs positioned outside the bad will have different features.

Multifocal and extended depth of focus lenses are not available in the NHS for routine care and so are outside the scope of this assessment.

4.4 Technology features

The focus of this assessment is on the impact of the lens materials and design features of the monofocal IOLs used for adults in cataract surgery. The lens selection recommendations in NICE guideline NG77 have been removed so that the more recent evidence for different lens materials and design features can be considered.

Monofocal IOLs are characterised by both the lens material and design features, and IOL selection depends on a person's visual goals, eye anatomy, IOL availability and clinician experience. Defining attributes include:

- Lens material: IOLs can be made from hydrophobic or hydrophilic materials, with both available to the NHS. Polymethyl methacrylate (PMMA) or silicone lenses are hydrophobic, while acrylic lenses can be either hydrophobic or hydrophilic. Material choice can influence outcomes, including rates of rates of posterior capsule opacification (PCO), and different optical aberrations. Hydrophobic IOLs are most commonly use in the NHS and were used in 77% of publicly-funded cataract surgeries between April 2015 and March 2020 (Ting et al., 2023).

- Optic edge shape: IOLs may have a rounded or square (sharp) optical edge, with square edge being most used. This can influence complication rates, such as PCO and edge glare (dysphotopsia).

- Insertion method and delivery system: IOLs can either be inserted manually, involving manual folding and forceps insertion, or injected. PMMA lenses are rigid, while silicone and acrylic lenses are foldable. Rigid lenses must be inserted manually, while foldable lenses can either be injected or manually inserted. Most IOLs are now injected, and these can either be pre-loaded (within the injector), semi-preloaded (within the cartridge but requiring insertion into the injector) or non-preloaded (requiring the lens to be manually folded and loaded into the injector). Both insertion method and delivery system can influence surgical efficiency, postoperative recovery, risk of complications, and visual outcomes.

- Haptic design: The lens is constructed from a central refractive optic and supporting arms known as haptics which hold the optic in place. Changes to the shape, material, and configuration of the supporting haptics can influence IOL stability, and the risk of complications.

- Lens structure: IOLs can be 1-piece (made of 1 material, designed for placement in the capsular bag), or 3-piece (made of different materials, able to be placed in multiple locations within the eye). This can influence refractive stability and complication rates and is usually determined by case complexity and intended placement within the eye.

- Surface shape: IOLs can have a spheric or aspheric surface shape. The surface shape directly impacts how light is focused on the retina. Surface shape can influence visual quality, in particular optical aberrations, contrast sensitivity (the ability to distinguish an object from its background) and night vision.

4.5 Innovative aspects

In addition to basic technology requirements and design features, monofocal IOLs may incorporate incremental features that build on standard functionality, as defined by the Department of Health and Social Care's medical technology innovation classification framework. Examples of innovative features include:

- Enhanced monofocal (also known as monofocal plus): These IOLs are designed with a higher-order aspheric profile which allows for a gradual increase in power from the edge to the centre of the lens, slightly increasing the range of focus. This results in moderately improved vision at intermediate distances and so can help to reduce dependence on glasses for daily activities, such as computer use.

- Toric: These lenses are designed to correct astigmatism, caused by an irregularly shaped cornea, that results in blurred or distorted vision. They feature a non-spherical shape with varying refractive powers.

- Blue-light filtering material: yellow-tinted IOLs are designed to filter out some of the violet and blue spectra of light and so give extra protection to the eye. Colour vision with these lens mimics the natural, yellowing of the human lens as it ages.

- Glistening free materials: advanced hydrophobic or hydrophilic acrylic polymers designed to eliminate microscopic, fluid-filled vacuoles (glistenings) that cause light scatter and visual disturbances.

The availability of these features varies across manufacturers, and not all features may be suitable or desirable for those undergoing cataract surgery. The list of features suggested for inclusion in this evaluation is not exhaustive and other features may be available to the NHS currently or in the future.

5. Comparator

The comparator for this assessment will be a monofocal IOL that meets the basic technology requirements (section 4.2 of the scope) but does not have innovative features. The monofocal IOL used in standard care in the NHS varies with patient characteristics. Based on the 3 most purchased IOLs through NHS Supply Chain, an IOL with the following attributes is typical of standard care:

- Material: hydrophobic acrylic
- Optic edge shape: square edge

- Insertion method and delivery system: injectable preloaded
- Lens colour: Clear
- Haptic configuration: C loop modified (if appropriate)
- Implant position: capsular bag (if appropriate)
- Design structure: 1 piece (if appropriate)

6. Patient and healthcare professional issues and preferences

People with cataracts value shared decision-making about their care (Bouaziz et al., 2022). NICE's Cataracts in adults: management guideline includes recommendations for sharing information with patients at referral, before, on the day of, and after cataract surgery. It is important the surgeon considers patient preferences for visual outcomes when selecting the IOL. This is to ensure that visual outcomes match their lifestyle preferences, such as independence from glasses for near or distance vision (Yeu and Cuozzo, 2021). A slight preference for distance vision has been shown among people having cataract surgery in the UK, but choice varies by individual (Jameel et al., 2023).

Evidence suggests that some people are not satisfied after cataract surgery (Charlesworth et al., 2022). People having cataract surgery through the NHS are only eligible for monofocal IOLs and need distance or near vision glasses for complete visual restoration after surgery. But some who do not need glasses before surgery for distance and/or near vision do not expect to need them afterwards (Matthew et al., 2005; Charlesworth et al., 2022). It is important to determine and manage people's expectations of cataract surgery.

In submissions made by people with lived experience, individuals highlighted the importance of visual outcomes and the ability to resume normal activities after surgery. The timeliness of surgery and appropriate follow-up care were also emphasised, alongside the need for information regarding alternatives to

surgery and what will happen if surgery is not chosen. Concerns relating to pain were also raised.

7. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

No equality issues relating specifically to the selection of IOL have been found. But equality issues exist which are related to getting cataracts, access to and the outcomes from cataract surgery as outlined below.

If cataracts cause a person substantial, long-term (over 12 months) difficulty with everyday activities, such as reading, driving, or working, they meet the criteria for a disability and are protected under the Equality Act (2010).

Some people with cataracts may need reasonable adjustments to access health services. This could include making information more accessible (easy-read or large-print letters) and environmental changes (ensuring proper lighting).

Cataracts affect some groups of adults disproportionately including older adults, women, adults with learning disabilities, some ethnic groups and adults with lower socioeconomic status. The occurrence of cataracts increases sharply with age, affecting 1 in 3 over the age of 65 in the UK (RCOPHTH,2021). Cataracts in adults are linked to reduced quality of life and cognitive decline (Assi et al., 2021;Xiong et al., 2023). Surgery has the potential to improve cognitive and wellbeing outcomes among this group (Pellegrini et al., 2020).

Adults with learning disabilities are up to 10 times more likely to have serious vision problems than the general population (RCOPHTH, 2015). Cataracts happen earlier and more frequently in some people with learning disabilities. This group may also be less able to communicate problems and successfully access eye care services (PHE, 2020). Challenges with assessing vision, and

concerns of perioperative complications can act as barriers to cataract surgery. Reasonable adjustments, such as changes in how vision is assessed, can help to overcome some barriers faced by people with learning disabilities.

Cataracts are more common in women than men. This is linked to both longer life expectancy and hormonal changes, such as reduced oestrogen after menopause (Wan et al, 2025). Around 57% of all NHS funded cataract surgeries in 2022 were performed in women (RCOPHTH, 2024).

Cataracts are more common in people from lower socioeconomic groups and their presenting symptoms tend to be worse (RCOPHTH, 2023;England et al., 2025). This has been linked to increased presence of ocular risks, such as lifestyle factors or occupational exposures (Yip et al., 2014). There is no strong evidence of access inequalities for cataract surgery among lower socioeconomic groups in England (Johnston et al., 2019). But, worse visual outcomes after surgery have been found for this group (Silvester et al., 2018).

Some ethnic groups are more likely to experience cataracts than others. For instance, people of Asian ethnicity have a greater risk of developing age-related cataracts with some evidence of an earlier onset (RCOPHTH, 2021).This has been linked to differences in exposure to some risk factors, such as some comorbidities (such as diabetes), sunlight, and dehydration (RCOPHTH, 2021).Data on differences in uptake of cataract surgery are not available according to ethnicity, but differences in surgery outcomes and complication rates have been noted (Mohite et al., 2024).

People's ethnic, religious, and socio-cultural background may affect their views towards cataract surgery. People with visual or hearing difficulties, cognitive impairment, a learning disability, people who are unable to read or understand health-related information (including people who cannot read English), or neurodivergent people may need additional support to understand information about cataracts, and the benefits and risks of surgery. Some people would benefit from support or information in languages other than English.

8. Guidance type

Monofocal IOLs for cataract surgery will be assessed for existing use. This approach to guidance development is selected because:

- the assessed group of technologies (interventions) comprise similar technologies, at least some of which would be considered established practice in the NHS (NICE HealthTech programme manual provides more detail on how established practice is determined)
- the technologies are potential incremental innovations, continuous improvements or copycat devices, as defined by the Department of Health and Social Care's medical technology innovation classification framework
- there is l variation in price between alternative technologies in the assessed group of technologies.

9. Decision problem

The key decision questions for this assessment are:

- Do differences in clinical and cost-effectiveness between alternative monofocal IOLs for cataract surgery justify price variation?
- Are there other factors that can inform decisions about which technology to purchase?

Table 1: Decision problem

Proposed type of assessment	Existing use
Population	Adults (18 years and over) undergoing cataract surgery. Potential subgroups include: • People with astigmatism who meet eligibility requirements for toric IOLs • People whose lifestyle is better suited to enhanced monofocal IOLs
Interventions	Monofocal IOLs available for purchase in the NHS. The lenses should meet all basic technology requirements (see section 4.2). They can have 1 or more innovative features.

Comparator	Monofocal IOLs that meet the basic technology requirements (see section 4.2), but do not have innovative features. Typical attributes include: • Material: hydrophobic acrylic • Optic edge shape: square edge • Insertion method and delivery system: injectable preloaded • Lens colour: Clear • Haptic configuration: C loop modified (if appropriate) • Implant position: capsular bag (if appropriate) • Design structure: 1 piece (if appropriate)
Setting	Secondary care setting (outpatient)
Outcomes and costs (may include but are not limited to)	Clinical outcomes: • Visual and refractive outcomes: • Visual acuity • Contrast sensitivity • Manifest Refraction Spherical Equivalent (MRSE) • Glare disability • Complication rates: - Posterior capsule opacification - IOL displacement • Post operative IOL rotation: - Requirement for additional procedures Patient-reported outcomes: • Health-related quality of life • Changes in spectacle dependence • Vision impact on daily life including both daily function and social factors • Patient satisfaction • Patient reported light related visual disturbances, such as flashes or glares (dysphotopsia) Costs and resource use: • Lens cost • Surgical equipment and consumable costs • Staff training cost • Complication treatment cost • Operational efficiency: - Procedure time - Preparation time • Monitoring costs and follow-up:

	- Post-operative clinic visits User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the user preference assessment.
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

10. Other issues for consideration

10.1 National Ophthalmology Database (NOD) Audit

The National Ophthalmology Database (NOD) Audit, managed by The Royal College of Ophthalmologists (RCOphth), captures and analyses data to monitor and improve patient outcomes, primarily focusing on cataract surgery and age-related macular degeneration (AMD) services in the UK. The NOD publishes an annual report on cataract surgery, with 8 versions currently available, and outcomes reported up to the 2023 NHS financial year.

NICE team

Aleix Rowlandson (topic lead), Bernice Dillon

Technical team

Bruce Smith, Ziad Asran

Project team

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