

[GID - HTE10090] Monofocal intraocular lenses for cataract surgery: existing use assessment

Final Protocol

Produced by: York Health Economics Consortium

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Date completed: 09/03/2026

1. Decision problem

Monofocal Intraocular Lenses (IOLs) for cataract surgery have been identified by NICE for assessment. The aim of this assessment is to evaluate the different features of monofocal IOLs, and if price differences are justified, with respect to clinical, economic and user preference outcomes. This document was prepared in response to the NICE Scope and presents the methods that the external assessment group (EAG) commissioned by NICE will undertake to produce the assessment.

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the [published scope](#) for the assessment.

Table 1. Summary table of the decision problem

Item	Description
Population	Adults (18 years and over) undergoing cataract surgery. Potential subgroups include: <ul style="list-style-type: none">• 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 of the scope). They can have 1 or more additional or innovative features.
Comparators	Monofocal IOLs that meet the basic technology requirements (see section 4.2 of the NICE scope), but do not have any innovative features. Typical attributes include: <ul style="list-style-type: none">• 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)

<p>Outcomes eligible for inclusion (may include but are not limited to)</p>	<p>Clinical outcomes:</p> <ul style="list-style-type: none"> • Visual and refractive outcomes: • Visual acuity • Contrast sensitivity • Manifest Refraction Spherical Equivalent (MRSE) • Glare disability • Complication rates: <ul style="list-style-type: none"> - Posterior capsule opacification - IOL displacement • Post operative IOL rotation: <ul style="list-style-type: none"> - Requirement for additional procedures <p>Patient-reported outcomes:</p> <ul style="list-style-type: none"> • 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) <p>Costs and resource use:</p> <ul style="list-style-type: none"> • Lens cost • Surgical equipment and consumable costs • Staff training cost • Complication treatment cost • Operational efficiency: <ul style="list-style-type: none"> - Procedure time - Preparation time • Monitoring costs and follow-up visits: <ul style="list-style-type: none"> - Post-operative clinic visits <p>User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the user preference assessment.</p>
<p>Economic analysis</p>	<p>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.</p> <p>Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results.</p>

	The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.
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1.1 Objectives

The purpose of this assessment is to address the following key decision questions:

- Do differences in clinical and cost-effectiveness between alternative monofocal IOLs for cataract surgery justify price variation?
 - What is the clinical effectiveness of standard or innovative features in monofocal IOLs?
 - What is the cost effectiveness of standard and innovative features in monofocal IOLs?
 - Are the prices charged by the manufacturers for monofocal lenses with innovative features justifiable in relation to the associated benefits?
- Are there other factors that can inform decisions about which technology to purchase?
 - What are the key gaps in the evidence for standard and innovative features in monofocal IOLs?

The final scope gives a list of examples of additional or innovative features. We may further describe and explore other features that are identified during the evidence review. The findings of this assessment are intended to be used by clinicians, commissioners, and adults having cataract surgery, to inform decisions about the choice of monofocal IOL.

2. Evidence review methods

2.1 Eligibility criteria

We will conduct a rapid review to identify the clinical and economic evidence that is available on monofocal IOLs for adult cataract surgery and explore if differences between lenses justify price variation and other factors that can inform decisions

about which technology to purchase. The review will be conducted using methods that conform to the NICE health technology evaluations manual and with reference to guidance from the NICE Decision Support Unit (NICE Decision Support Unit 2025). The review will follow the principles of conducting a rapid review published in the Cochrane Handbook (Higgins et al. 2011). The review methods, search approach, and synthesis will be conducted in a transparent manner. Searches developed for the purposes of the evidence review will be devised by an experienced information specialist and quality assured by a second information specialist. The evidence review will involve searches to identify published evidence relevant to the decision problem, including:

- Studies reporting clinical outcomes, adverse events and patient-reported outcomes for people who have received monofocal IOLs for cataract surgery.
- Existing economic evaluations of relevant monofocal IOLs for cataract surgery.
- Healthcare cost and resource use data published in economic evaluations of monofocal IOLs for cataract surgery.

We will also incorporate any relevant evidence submitted by manufacturers through the NICE request for company evidence.

Records will be screened according to the eligibility criteria described in Table 2. Inclusion and exclusion criteria. Relevant clinical and health-related quality of life (HRQoL) data will inform the parameters of the economic model (see Section 3).

Inclusion criteria

The eligibility criteria for the review of clinical and economic evidence are summarised in Table 2. These criteria were informed by the decision problem set out in the [NICE scope](#), discussion with the NICE team, and feedback from stakeholders to this assessment given in the scoping workshop.

Table 2. Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Population(s)	Adults (18 years and over) with cataracts in one or both eyes, whose eyesight, quality of life, or ability to	<ul style="list-style-type: none"> • Children and young people aged <18 years. • People without cataracts.

	perform daily tasks is significantly impaired ¹ .	<ul style="list-style-type: none"> • People with paediatric cataract (onset prior to age 16 years).
Subgroup(s)	<p>Subgroup data for the following adult populations will be eligible where reported:</p> <ul style="list-style-type: none"> • People with astigmatism who meet eligibility requirements for toric intraocular lenses (IOLs). • People whose lifestyle is better suited to enhanced monofocal IOLs. 	Other subgroups will be considered ineligible for data extraction.
Intervention	<p>Monofocal IOLs available for purchase in the NHS. These can include:</p> <ul style="list-style-type: none"> • Standard. • Enhanced. • Toric. • Toric enhanced. <p>Lenses made from materials including but not limited to:</p> <ul style="list-style-type: none"> • Hydrophobic acrylic. • Hydrophilic acrylic. • Polymethyl Methacrylate (PMMA). <p>With optic edge shapes including but not limited to:</p> <ul style="list-style-type: none"> • Square (sharp) edge (variable degrees). • Round edge. <p>With optical surface shapes including but not limited to:</p> <ul style="list-style-type: none"> • Spheric. • Aspheric. <p>With haptic configurations including but not limited to:</p> <ul style="list-style-type: none"> • C-loop e.g. modified C-loop. • Plate. • Closed loop. • Z-loop. <p>In one of the following physical architectures:</p> <ul style="list-style-type: none"> • One-piece design. 	Monofocal IOLs other than those listed as eligible.

	<ul style="list-style-type: none"> • Three-piece design. <p>With one of the following delivery systems:</p> <ul style="list-style-type: none"> • Manual insertion. • Injectable (pre-loaded within the injector, semi-preloaded within the cartridge but requiring insertion into the injector, or non-preloaded requiring manual insertion into the injector). <p>With none, one, or more of the following innovative features:</p> <ul style="list-style-type: none"> • Material e.g. glistening-free, UV-filter. 	
Comparators	<p>Monofocal IOLs that meet the basic technology requirements, but do not have additional design or innovative features. Typical attributes include:</p> <ul style="list-style-type: none"> • 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). 	N/A
Outcomes eligible for inclusion (organised by outcome type)	<p><u>Clinical outcomes</u></p> <ul style="list-style-type: none"> • Visual acuity measures, including but not limited to: <ul style="list-style-type: none"> ○ Contrast sensitivity (e.g. Peli-Robson chart). ○ Manifest Refraction Spherical Equivalent (MRSE). ○ Glare disability. ○ Lens centration. • Complication rates: <ul style="list-style-type: none"> ○ Posterior capsule opacification. ○ IOL displacement. <p><u>Patient-reported outcomes</u></p> <ul style="list-style-type: none"> • Health-related quality of life. 	Outcomes not aligned to these categories.

	<ul style="list-style-type: none"> • 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) <p><u>Cost outcomes</u></p> <ul style="list-style-type: none"> • IOL costs (including surgical equipment and consumables). • Complication costs. • Operational efficiency: <ul style="list-style-type: none"> ○ Procedure time. ○ Preparation time. • Monitoring costs and follow-up visits. • Staff training costs. • Key outcomes from economic evaluations (model characteristics, base case results, sensitivity analyses reported). 	
Study design²	<p>For the clinical review:</p> <ul style="list-style-type: none"> • RCTs and quasi-randomised studies. • Meta-analyses.³ <p>For the economic review:</p> <ul style="list-style-type: none"> • Cost-effectiveness analyses (including cost-utility analyses). • Cost-benefit analyses. • Cost-consequence analyses. • Cost-comparison analyses. • HTA reports investigating the cost-effectiveness of treatments. <p>Other study designs may be considered (such as prospective studies reporting comparative evidence) if a low volume of evidence is available e.g. for specific features.</p>	<ul style="list-style-type: none"> • Systematic reviews without meta-analysis.⁴ • Narrative reviews. • Prospective or retrospective observational studies. • Time series analyses. • Case reports. • Bench studies.
Setting	<ul style="list-style-type: none"> • Secondary care setting (outpatient), including NHS 	<ul style="list-style-type: none"> • Primary care (GP practice).

	<p>treatment centres and Independent Sector Providers.</p> <ul style="list-style-type: none"> • Community (including community hospitals). • 	
Limits	<ul style="list-style-type: none"> • Full text English language publications limited to 2001 to date. • Economic evaluations limited to 2016 to date. 	<ul style="list-style-type: none"> • Conference abstracts. • Non-English language publications. • News items, opinion pieces and editorials.

Key: EAG, External Assessment Group; GP, General Practitioner; HTA, Health Technology Assessment; IOL, Intraocular Lens; MRSE, Manifest Refraction Spherical Equivalent; NHS, National Health Service; PCO, Posterior Capsule Opacification; PMMA, Polymethyl Methacrylate; RCT, Randomised Controlled Trial; UV, Ultraviolet.

¹ People with cataracts developing for any ocular or non-ocular co-pathology e.g. age-related, uveitis, diabetes mellitus, etc.

² Should insufficient evidence be identified that meets the listed inclusion criteria for specific lens features, additional targeted searches will be conducted.

³ Most recent meta-analyses and systematic reviews with meta-analyses that target the population of interest or relevant subgroup.

⁴ Systematic reviews without meta-analyses published in the last 3 years will be checked for relevant references.

2.2 Search strategy

A single set of searches will be conducted to identify evidence on clinical and economic outcomes.

Reflecting the NICE HealthTech programme manual for existing-use assessments methods will incorporate some elements of Cochrane rapid review methodology (Garritty et al. 2024). Searches will be conducted systematically (the searches will be conducted in a methodical pre-planned way; will be appropriately transparent and reproducible; and will be designed to be appropriately robust for the project context). The selection of search resources will be limited to allow the reviews to be completed within the HealthTech existing-use guidance context.

A MEDLINE (OvidSP) search strategy designed to identify studies of monofocal lenses in cataract surgery is presented in Appendix A.

The strategy comprises seven concepts:

- Cataract surgery (search lines 1 to 13).
- Monofocal lenses (search lines 14 to 21).

- Lens design features (search lines 22 to 43).
- Eligible brand names (search line 44).
- SRs/MAs (search lines 46 to 68)
- RCTs (search lines 69 to 76).
- Economic evaluations (EEs) (search lines 79 to 95).

The concepts are combined as follows: cataract surgery AND (monofocal lenses OR lens design features OR eligible brand names) AND (SRs/MAs OR RCTs OR EEs).

The strategy was devised using a combination of subject indexing terms and free text search terms in the Title, Abstract and Keyword Heading Word fields. The search terms were identified through discussion within the research team, scanning background literature and browsing database thesauri.

The search terms for lens design features include terms for generic and specific features. These terms have, in some cases, been intentionally restricted to achieve manageable screening numbers. The terms for design features have been supplemented by the names of eligible brand names to provide a further route to retrieval of relevant studies. This list may not be exhaustive (containing every brand of lens available within the NHS) but as it is intended to provide an additional route to identifying relevant studies we don't anticipate this preventing retrieval of relevant studies.

The search terms for the SRs/MAs concept (search lines 46 to 68) are based on the search filter for SR / MA / HTA / ITC published by Canada's Drug Agency (CDA-AMC) (Canada's Drug Agency 2026). The published filter has a multiform design making it compatible with searching several databases at once. Amendments have been made to remove the non-MEDLINE terms.

The search terms for the RCT concept (search lines 69 to 76) are based on the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity-maximising version (2008 revision); Ovid format (Lefebvre C 2024). Two changes have been made to the published filter to enhance potential

sensitivity. Line 71 has been changed from randomized.ab. to (randomiz* or randomis*).ti,ab. Line 74 has been changed from randomly.ab. to randomly.ti,ab.

The search terms for the economic evaluations concept (search lines 79 to 95) are based on the filter developed by the University of York Centre for Reviews and Dissemination (CRD) for identification of economic evaluations to include in NHS Economic Evaluation Database (NHS EED) (Centre for Reviews and Dissemination 2008).

The strategy excludes animal studies from MEDLINE using a standard algorithm (search line 99). The strategy also excludes some ineligible publication types which are unlikely to yield relevant study reports (editorials, news items and case reports) and records with the phrase 'case report' in the title (search line 100).

The EE terms are restricted to studies published from 2016 to date (search line 97). Any relevant studies reporting economic outcomes published before this date will be sourced from NG77 (NICE 2017) if required. Reflecting the eligibility criteria the SR and RCT terms are limited to studies published from 2001 to date (search line 78) Reflecting the eligibility criteria, the whole strategy is restricted to studies published in English language (search line 103).

The final Ovid MEDLINE strategy will be peer-reviewed before execution by a second Information Specialist. Peer review will consider the appropriateness of the strategy for the review scope and eligibility criteria, inclusion of key search terms, errors in spelling, syntax and line combinations, and application of exclusions.

We will conduct the literature search in the databases shown in Table 3. In accordance with rapid review methodology, a limited selection of resources have been prioritised to achieve manageable screening numbers that suit the available timelines and resources. CENTRAL is a highly concentrated source of reports of randomised controlled trials and quasi-randomised controlled trials, the majority of which are sourced from MEDLINE and Embase. EconLit will be searched to supplement the retrieval of economic evidence.

Table 3: Proposed databases and information sources

Resource	Interface / URL
Databases	
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Cochrane Database of Systematic Reviews (CDSR)	Cochrane Library/Wiley
Cochrane Central Register of Controlled Trials (CENTRAL)	Cochrane Library/Wiley
EconLit	OvidSP
National Ophthalmology Database (NOD) Audit website	https://nodaudit.org.uk/publications
Reference list checking	n/a
Company Submission Evidence	n/a

The NOD Audit website will be screened for relevant peer-reviewed publications and audit reports that meet the eligibility criteria. Published and unpublished studies provided by companies and other stakeholders will also be considered and included if relevant to the decision problem.

We will conduct searches using each database or resource listed in the protocol, translating the agreed Ovid MEDLINE strategy appropriately. Translation includes consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The approach taken to strategy translation may incorporate some pragmatic elements, as appropriate to HealthTech existing-use guidance timelines and resources. The final translated database strategies will be peer-reviewed by a second Information Specialist. Peer review will consider the appropriateness of the translation for the database being searched, errors in syntax and line combinations, and application of exclusions.

Reflecting the NICE HealthTech programme manual for existing-use assessments methods will incorporate some elements of Cochrane rapid review methodology (Garritty et al. 2024). Searches will be conducted systematically (the searches will be

conducted in a methodical pre-planned way; will be appropriately transparent and reproducible; and will be designed to be appropriately robust for the project context).

2.3 Study selection

Four levels of screening will be used to select relevant evidence for the assessment:

Level 1: A single researcher will assess the search results according to their relevance in providing information on clinical and cost-effectiveness of the lens technology features and will remove the obviously irrelevant records such as those about ineligible diseases.

Level 2: A single researcher will assess the titles and abstracts of remaining records for relevance against the eligibility criteria, with a sample of 20% of records double-checked by a more senior reviewer.

Level 3: We will obtain the full text of potentially relevant studies. A single researcher will assess the full texts for relevance against the eligibility criteria, with a sample of 20% of papers double-checked by a more senior reviewer.

During study selection:

- We will record the number of records included and removed at each selection stage in the PRISMA flow diagram. We will list studies excluded after assessment of the full document in an excluded studies table, with the reasons for exclusion.
- Where results for one study are reported in more than one paper, all related papers will be identified and grouped together to ensure that participants in individual studies are only included once.
- To guide the prioritisation of studies at level 4, included studies will be tagged using relevant categories such as study location, sample size and study quality.

Level 4: A final list of included studies will be prioritised for data extraction from those included at Level 3, depending on the volume of evidence base identified. Criteria for prioritisation will be determined based on the available evidence, but may include the following for clinical evidence: study location (e.g. UK, Europe, Canada), studies with no obvious quality concerns (e.g. selection bias, high rates of missing

data), studies with larger sample sizes, study date, and studies addressing gaps in the prioritised evidence (e.g. evidence for intervention features for which no studies have yet been prioritised for inclusion). For certain lens features, the level and availability of evidence may vary and prioritisation by study design may therefore vary according to the lens features.

Reasons why studies were not prioritised for extraction will be noted and reported in the appendix of the report.

2.4 Data extraction strategy

A data extraction template will be developed in Word and piloted on 3 included studies. Following any changes made as a result of the pilot, the data extraction template will be finalised. One researcher will extract data from included studies (following prioritisation, if applied) and a second researcher will check all data points. Any discrepancies will be resolved by discussion, or the involvement of a third researcher when required. Data extraction will be targeted to the most relevant study characteristics including bibliographic details, study design, key patient characteristics, key intervention / comparator characteristics, and outcomes (grouped by clinical, patient-reported and economic). Where studies report an outcome in multiple formats and at multiple timepoints, we will extract formats most likely to be comparable across studies.

2.5 Quality assessment strategy

Quality assessment will be conducted in accordance with [Section 3 of NICE's health technology evaluations manual](#). One reviewer will assess the risk of bias of each included study using a relevant, validated tool for each study design (e.g. Cochrane RoB 2 for RCTs, and the Drummond Checklist for economic evaluations). A second reviewer will check the risk of bias assessment.

We will summarise the results of the risk of bias assessment in a table and we will provide a detailed assessment in an Appendix to the main report. In the discussion section of the report, we will comment on the generalisability of results to clinical practice in the NHS.

2.6 Methods of synthesis and analysis

Studies included for data extraction will be summarised in tables presenting their methods and results. Clinical and economic evidence will be presented and discussed in separate subsections. We will provide a narrative summary exploring the quality of the studies, the relationship between studies and patterns that we have discerned across studies. We will provide an overall assessment of the strength of the evidence base in relation to the decision questions. If the evidence allows, we will also comment on the evidence for the population subgroups detailed in the inclusion criteria.

Any remaining eligible studies deprioritised for data extraction (i.e. those not included in the narrative summary) will be tabulated in an appendix, with brief details for each study.

3. Economic analysis methods

We propose the development of an economic model to estimate the clinical and economic outcomes associated with the use of monofocal IOLs with different features such as the lens material or optic edge shape. The model is expected to capture a population of adults with cataracts whose eyesight, quality of life, or ability to perform daily tasks is significantly impaired.

The model will address the decision problem outlined in the final scope (see Section 1 for the decision problem).

The primary aim of this economic analysis is to estimate the costs and clinical outcomes for monofocal IOLs for cataract surgery that meet all basic technology requirements and use typical attributes as identified in the NICE Scope. We will then compare the outcomes for different lens materials and design features of monofocal IOLs, to evaluate if price differences between lenses with differing features are justifiable. The model will also identify key drivers of costs and clinical outcomes. Fully incremental analysis will be included to compare different IOLs and features, if sufficient evidence is available.

We will also consider the costs and clinical outcomes in specific subgroups of those in receipt of enhanced monofocal IOLs or toric IOLs, where data is available.

Additionally, we will perform scenario analyses around any potential data gaps that may arise, to account for uncertainties within the model.

The economic evaluation will adopt an NHS and Personal Social Services (PSS) perspective, in line with NICE guidelines (National Institute for Health and Care Excellence 2025).

3.1 Model development

This evaluation will include a feature-based assessment of IOLs used in cataract surgery within the healthcare system. This analysis may include specific subgroups such as people with astigmatism who meet eligibility requirements for toric IOLs or people whose lifestyle is better suited to enhanced monofocal IOLs. We anticipate there will be differences in the level and quality of evidence available across subgroups. This is particularly the case for people with a preference for elongated focal point, given this may be down to patient choice, and identifying a suitable comparator (where the population is the same) may be challenging. Where evidence gaps are identified, we will reference and interpret this in the final report. Where appropriate, this will be used to inform recommendations for future data collection.

Expert clinical input will be used to guide the model design, use of subgroups, and to ensure that key clinical events and outcomes are appropriately captured. We will aim to include all outcomes listed in the NICE Scope that either have suitable evidence to inform them, or where informed assumptions can be used. Outcomes will be prioritised based on expert clinical input on their importance and available evidence. Those outcomes with greater uncertainty may be included in additional scenario analyses.

Model inputs will be informed by published literature, information provided by companies, NHS data sources, and expert opinion. To identify appropriate evidence for costs and resource use, we will conduct targeted searches of the economic literature, supplemented by data from the NHS Cost Collection data, the Unit Costs of Health and Social Care published by the Personal Social Services Research Unit (PSSRU), and the British National Formulary (BNF). All costs will be inflated to the 2024/25 price year. Cost and health outcomes will be discounted at 3.5% per annum, in line with NICE guidance.

While the model will include health-related quality of life outcomes (HRQoL) where available, particularly in the long-term, it may not be possible to fully reflect the impact of innovative features associated with monofocal IOLs. This is especially evident for certain side effects of cataract surgery that are either extremely rare or do not have long-term impacts on HRQoL or visual function. Where we are unable to quantify this, these issues will be discussed qualitatively in the final report. Equally, we acknowledge that broader societal outcomes may not be captured in the model, such as changes in optician visits or new prescription glasses. These outcomes will also be discussed qualitatively in the final report.

Where appropriate and feasible (based on available data), sensitivity analyses will be undertaken to explore uncertainty. These may include one-way and multi-way sensitivity analyses and use of probabilistic sensitivity analyses (PSA). The use of PSA involves sampling of parameter inputs from distributions that characterise uncertainty in the mean estimate of the parameter. PSA is used to characterise uncertainty in a range of parameter inputs simultaneously, to consider the combined implications of uncertainty in parameters.

Additional scenario analysis may also be conducted around key factors such as the rate of posterior capsule opacification (PCO) stratified by hydrophilic and hydrophobic lenses, to outline the impact on the results. Key scenarios will be decided in consultation with clinical experts. For instance, this may include different assumptions or data informing the decline of visual acuity post cataract surgery, which may interact with specific lens features.

3.2 Conceptual modelling

A conceptual model will be developed to address the decision problem. While it is not possible at this point to provide a definitive outline of the model structure, we propose that the model is likely to be a de novo patient-level simulation (PLS) with a lifetime time horizon to allow us to capture long-term outcomes. It is likely that we can leverage structural elements from previous health economic analysis conducted as part of NG77, a NICE guideline for cataracts in adults (NICE 2017). The exact model structure used as part of the NG77 will not be suitable for this evaluation, given the different decision problem answered looking at overall cataract management. However, we expect similar outcomes to be captured.

The model structure will be finalised following further exploration of the clinical pathways and the evidence assessment. There will be trade-offs between more standard Markov approaches, and a PLS model, which will be considered as part of the assessment period, and will inform the optimal model choice.

For instance, cohort modelling methods such as Markov models are challenging to reflect continuous changes in visual acuity in both eyes at different time points, which lens features are likely to impact. A larger driver of health-related quality of life (HRQoL) is the condition of the stronger eye, therefore, it is important to capture the relationship between both eyes, if features are linked to overall visual acuity (Claxton et al. 2017). Additionally, Markov models do not have the ability to retain memory. Therefore, a person's baseline characteristics or previous history are unable to be captured without the introduction of additional health states or assumptions, potentially adding additional uncertainty into the model. This is important when an event occurring (such as PCO) can be linked to other relevant economic outcomes.

PLS models account for these limitations by modelling individuals independently allowing for continuous visual acuity scores for both eyes, historic risk factors and other characteristics to be incorporated in the analysis. From initial scoping, we believe that different monofocal IOLs will likely impact longer term visual acuity, and will impact future risk of events, which may be interlinked. However, if the monofocal IOL is not specifically impacting some longer-term outcomes such as visual acuity, it may be possible to simplify the model to a cohort structure. This will be explored early in the assessment period when considering the evidence.

The modelling approach will capture the value and impact of specific lens features, where data is available. Where possible, features including hydrophilic and hydrophobic lens material will be analysed to see the potential impact on long term outcomes. It is anticipated that there may be limited evidence to inform the economic and clinical outcomes of some of the features. Therefore, where features could not be addressed in the economic analysis, they will be commented on qualitatively, or scenarios may be informed from insights gained through the user preference assessment.

The outlined approach to consider the economic model enables us to balance the use of existing evidence, capture both short-term events and select long-term cost and health outcomes, while tailoring the structural approach to the required complexity that is needed for a useful assessment.

Once the model structure and key assumptions have been refined based on the final scope and evidence review, we will validate the approach with clinical experts. This will be done through dedicated meetings or email correspondence. Expert feedback will be used to test the face validity of the conceptual model, inform subgroup analysis, and ensure that key events and outcomes are appropriately captured.

4. User Preference Assessment

In parallel to the clinical evidence review and economic analysis, the EAG will perform a user preference (UP) assessment to identify criteria related to features of the technology or its performance (preference criteria) that influence the preferences of users. Users are people whose experience with the technologies would allow them to make informed choices between different options. This assessment is expected to include healthcare professionals responsible for selecting monofocal IOL for cataract surgery, such as ophthalmologist surgeons or optometrists.

Two virtual workshops will be held, and two email exercises will be conducted by the EAG as part of the user preference assessment (**Error! Reference source not found.**).

Table 4: User preference assessment stages

Stage	Objective
Workshop 1	<ul style="list-style-type: none">To identify and validate key factors that are important to users when selecting monofocal IOL
Email Exercise 1	<ul style="list-style-type: none">To determine an average rank for each criterion identified, in order of most to least important, using SMART
Email Exercise 2	<ul style="list-style-type: none">To determine the weight (relative importance) of each criterion, using the swing weighting technique (which may include weighing only the top 10 ranked criteria)
Workshop 2	<ul style="list-style-type: none">To define 'performance rules', which can describe how each criterion is measured

Abbreviations: IOL, intraocular lens; SMART, simple multi-attribute ranking technique.

The outputs of the assessment are intended to supplement the clinical and economic evidence review, as well as the economic analysis, capturing stakeholder perspectives and preferences that would otherwise not be represented in the evidence base for the committee's consideration. The UP assessment will culminate with a performance matrix, including a ranked and weighted list of preference criteria and performance rules for assessing 'success' within these criteria.

The findings, including the final performance matrix, will be presented in the EAG assessment report, alongside the clinical evidence review and health economic analysis. Outcomes identified during the UP assessment will, if feasible, be

implemented by the EAG into the clinical evidence review, synthesis and health economic analysis. Should these outcomes be anticipated to have a meaningful effect on HRQoL, costs or relative effectiveness, they may also be incorporated as additional scenario analyses. While clinical presentation and external criteria will not be included in the performance matrix, they will contribute to the narrative understanding of decision-making surrounding monofocal IOL for cataract surgery and, thus, will be reported.

5. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders will be considered by the EAG if received by 24th of March 2026. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any 'commercial in confidence' data provided by a company and specified as such will be highlighted in **blue and underlined** in the assessment report. Any 'academic in confidence' data provided by a company, and specified as such, will be highlighted in **yellow and underlined** in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values).

6. Competing interests of authors

The EAG can confirm that there are no conflicts of interests to declare for the project team, or the company as a whole.

7. References

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Appendix A: Draft search strategy

Draft search strategy for Ovid MEDLINE® ALL

- | | | |
|---|---|-------|
| 1 | exp cataract extraction/ | 39437 |
| 2 | cataract/ | 34473 |
| 3 | cataract*.ti,ab,kf. | 73423 |
| 4 | ((lens* or lenticular) adj5 (opaci* or cloud* or aspirat* or excis* or operat* or remov* or surg* or extract*)).ti,ab,kf. | 17537 |

- 5 enzymatic zonulolys*.ti,ab,kf. 151
- 6 (phakectom* or phacectom*).ti,ab,kf. 8
- 7 capsulorhex*.ti,ab,kf. 1634
- 8 capsulorrhex*.ti,ab,kf. 234
- 9 (phacoemulsification* or phakoemulsification*).ti,ab,kf. 12176
- 10 ((lens* or lenticular or phaco or phako) adj3 (emulsification* or emulsion*)).ti,ab,kf. 137
- 11 ((zonula or zonule) adj3 dissolution*).ti,ab,kf. 1
- 12 zonulys*.ti,ab,kf. 52
- 13 or/1-12 96767
- 14 lens implantation, intraocular/ 14847
- 15 lenses, intraocular/ 17771
- 16 pseudophakia/ 3014
- 17 ((artificial* or prosth*) adj5 lens*).ti,ab,kf. 1055
- 18 (pseudophak* or pseudo-phak*).ti,ab,kf. 5443
- 19 or/14-18 29752
- 20 (monofocal* or mono focal* or standard or single focus* or single focal* or monofocus* or mono focus*).ti,ab,kf. 1286160
- 21 19 and 20 2762
- 22 (monofocal* plus or mono focal* plus or toric plus).ti,ab,kf. 16
- 23 ((enhanc* or extend* or advanc* or improve*) adj5 (iol or iols or lens* or intra-ocular or intraocular*)).ti,ab,kf. 6508

- 24 ((monofocal* or mono focal* or standard or single focus* or single focal* or monofocus* or mono focus*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 2582
- 25 (toric adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 1944
- 26 ((hydrophil* or hydrophob* or hydro phob* or hydro phil* or hydrogel*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 3596
- 27 exp prosthesis design/ 67417
- 28 exp "hydrophobic and hydrophilic interactions"/ 49472
- 29 exp hydrogels/ 47522
- 30 polymethyl methacrylate/ 8870
- 31 silicones/ 13845
- 32 acrylic resins/ 25307
- 33 acrylates/ 9028
- 34 ((square* edg* or round* edg* or edg* profil* or sharp* edg* or optic* edg*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 239
- 35 ((glisten* or microvacuole* or vacuole* or mv or mvs) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 249
- 36 ((material* or design* or coat* or compos* or surface*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 11880
- 37 ((acron* or bone cement* or implast* or kallocryl* or lucite* or methyl acrylic* or methyl methacrylate polymer* or methyl polymethacrylate* or methylpolymetacrylate* or palacos* or palavit* or paraloid* or perspex* or plexiglas* or plexiglass* or pmma* or poly methacrylic acid* or poly methyl methacrylate* or poly methylmethacrylate* or polymethacrylic acid methyl* or polymethyl methacrylate* or polymethylene methacrylate* or polymethylenemethacrylate* or

polymethylmetacrylate* or polymethylmethacrylate* or superacryl*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 1302

38 ((silicone* or silastic*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 2438

39 ((acrylate* or acrylic* or polyacrylate* or polyacrylic*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 1715

40 ((spheric* or aspheric* or shape* or loop* or haptic* or plate* or piece* or angul* or angle* or planar* or offset*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 9555

41 ((blue* or yellow* or light* or colour* or color* or UV or ultra violet or ultraviolet) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 4687

42 ((manual* or load* or preload* or semipreload* or screw* or automat* or deliver* or inject* or fold* or forcep* or insert*) adj5 (iol or iols or lens* or intra-ocular or intraocular*).ti,ab,kf. 8608

43 or/21-42 248518

44 (1stq*2 or acrysof*2 or aiala dry*2 or akreos*2 or artis*2 or c flex*2 or clareon*2 or clearview*2 or ct asphina*2 or ct lucia*2 or ct spheris*2 or envista*2 or exmoor monofocal*2 or intensity monofocal*2 or ipure*2 or isopure*2 or lucent*2 or matrix acrylic*2 or medicontur*2 or micropure*2 or mirado*2 or osi pmma*2 or podeye*2 or rayone*2 or seelens*2 or sensar*2 or softec*2 or superflex*2 or technis*2 or vision matrix pmma*2 or vistazo*2 or ajl pmma*2 or aspira-aa*2 or at torbi*2 or bunnylens*2 or biconvex pmma iol*2 or eyecee*2 or loop guardian*2 or loop keeper*2 or luxgood*2 or torica-aa*2 or vivinex*2).ti,ab,kf,ot. 13154

45 13 and (43 or 44) 15433

46 (systematic review or meta-analysis).pt. 408427

47 meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or exp technology assessment, biomedical/ or network meta-analysis/ 456957

- 48 ((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf. 469286
- 49 ((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab,kf. 22528
- 50 ((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf. 51114
- 51 (data synthes* or data extraction* or data abstraction*).ti,ab,kf. 57404
- 52 (handsearch* or hand search*).ti,ab,kf. 12368
- 53 (mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf. 44202
- 54 (met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf. 15168
- 55 (meta regression* or metaregression*).ti,ab,kf. 20782
- 56 (meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw. 631027
- 57 (medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw. 475040
- 58 (cochrane or (health adj2 technology assessment) or evidence report).jw. 23191
- 59 (comparative adj3 (efficacy or effectiveness)).ti,ab,kf. 24194
- 60 (outcomes research or relative effectiveness).ti,ab,kf. 12941
- 61 ((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf. 5377
- 62 (multi* adj3 treatment adj3 comparison*).ti,ab,kf. 350
- 63 (mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf. 190

64 umbrella review*.ti,ab,kf. 3499

65 (multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf. 18

66 (multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf. 21

67 (multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf. 16

68 or/46-67 919086

69 randomized controlled trial.pt. 655394

70 controlled clinical trial.pt. 95761

71 (randomiz* or randomis*).ti,ab. 989957

72 placebo.ab. 267175

73 clinical trials as topic.sh. 206993

74 randomly.ti,ab. 482590

75 trial.ti. 360835

76 or/69-75 1857875

77 45 and (68 or 76) 1954

78 limit 77 to yr="2001 -Current" 1625

79 economics/ 27558

80 exp "costs and cost analysis"/ 285952

81 economics, dental/ 1922

82 exp economics, hospital/ 26442

83 economics, medical/ 9323

84 economics, nursing/4015

85 economics, pharmaceutical/ 3178

86 (economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic*).ti,ab. 1294081

87 (expenditure* not energy).ti,ab. 43107

88 value for money.ti,ab. 2514

89 budget*.ti,ab. 41618

90 or/79-89 1470244

91 ((energy or oxygen) adj cost).ti,ab. 5290

92 (metabolic adj cost).ti,ab. 2000

93 ((energy or oxygen) adj expenditure).ti,ab. 32476

94 or/91-93 38619

95 90 not 94 1461228

96 45 and 95 336

97 limit 96 to yr="2016 -Current" 192

98 78 or 97 1779

99 exp animals/ not humans/ 5427969

100 (news or editorial or case reports).pt. or case report.ti. 3575781

101 or/99-100 8935845

102 98 not 101 1713

103 limit 102 to english language 1607

Key to Ovid symbols and commands:

*	Unlimited right-hand truncation symbol
*N	Limited right-hand truncation - restricts the number of characters following the word to N
ti,ab,kf,ot	Searches are restricted to the Title (ti), Abstract (ab), Keyword Heading Word (kf) and Original Title (ot) fields
adj	Retrieves records that contain terms next to each other (in the shown order)
adjN	Retrieves records that contain terms (in any order) within a specified number (N) of words of each other
/	Searches are restricted to the Subject Heading field
exp	The subject heading is exploded
or/1-12	Combines sets 1 to 12 using OR
yr	Searches are restricted to the Year of Publication field

Saved in Ovid as: temp - MTAC411 - intraocular lens - MEDLINE 05032026 SR-RCT-EE