NHS
Cheshire and Merseyside

# Clinical Commissioning Policy

## CMICB_Clin097
Cataract Surgery

### Category 2 Intervention - Only routinely commissioned when specific criteria are met

Contents



**Last Reviewed:** March 2024

*This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.*

# 1. Policy statement

1.1 Multifocal intraocular lenses are not routinely commissioned.

1.2 Cataract surgery is routinely commissioned if the patient meets one of the following criteria:

1.2.1 An assessment of the patient's visual quality of life (using the local assessment tool below) suggests surgery is appropriate:

**Local Visual Quality of Life Assessment Tool**

| Questions | Responses (a) | Responses (b) | Responses (c) |
|---|---|---|---|
| **1. How well can the patient see objects in the distance?** | *Without difficulty* | *With slight difficulty* | *With great difficulty* |
| **2. How well can the patient read writing on the TV and/or road signs?** | *Without difficulty* | *With slight difficulty* | *With great difficulty* |
| **3. How well can the patient recognise people on the street?** | *Without difficulty* | *With slight difficulty* | *With great difficulty* |
| **4. How well can the patient read from newspapers/books?** | *Without difficulty* | *With slight difficulty* | *With great difficulty* |
| **5. How often does the patient suffer from glare at night?** | *Rarely/Never* | *Occasionally* | *Most of the time* |

***Interpretation***

1. *If answer to question 4 is b or c, this is often an indication of macular problems rather than cataract. If this is the only problem, referral for cataract surgery may be inappropriate and an opinion on maculopathy could be required,*
2. *If answers to questions 1 to 3 are mainly (c), this is probably cataract-related and referral may be appropriate,*
3. *If glare is the ONLY problem (question 5), the referrer (after discussion with the patient) will need to make a judgement as to the potential impact of cataract removal (particularly if the patient drives) before deciding whether surgery is appropriate.*

**OR**

1.2.2 Patient has significant optical imbalance (anisometropia or anisekonia) following cataract surgery on the first eye.

**OR**

1.2.3 Patient has glaucoma and requires cataract surgery to control intra ocular pressure.

**OR**

1.2.4 Patient has diabetes and requires clear views of their retina to look for retinopathy.

**OR**

1.2.5 Patient has wet macular degeneration or other retinal conditions and requires clear views of their retina to monitor their disease or treatment (e.g. treatment with anti-VEGFs).

**AND in all cases**

1.2.6 Fitness for surgery is considered to be adequate

**AND**

1.2.7 Details of the procedure, potential benefits and risks have been explained to the patient and the patient is willing and consents to proceed.

# 2. Exclusions

2.1 None.

# 3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

# 4. Rationale behind the policy statement

4.1 In accordance with NICE guideline NG 77 (management of cataracts in adults), the policy statements do not specify visual acuity as a referral criterion. Visual acuity per se is regarded as an imperfect measure of sight -related quality-of-life and there are other factors which should be taken into account.

4.2 Similarly, NG 77 recommends that multifocal lenses should not be offered for people having cataract surgery as their use is not supported by the evidence base.

4.3 Because there are no published, validated tools available to predict the optimal cohort of people most likely to benefit from surgery, the visual quality-of-life assessment tool is being utilised. This pragmatic questionnaire was developed using the combined skills and experience of several ophthalmologists based across the region. The policy statement, therefore, represents a consensus amongst local experts in the field.

4.4 A comprehensive literature review on cataract surgery came up with the following main conclusions:

4.1.1 Various cost utility analyses have consistently demonstrated that the costs per QALY for cataract surgery are well below NICE's maximum limit of cost effectiveness. This is irrespective of 1st eye, 2nd eye or age and the procedure is still considered to be cost effective even in those least likely to benefit.

4.1.2 Currently, there is no validated pre-and/or post assessment tool to determine which cohort (if any) are most likely to derive benefit from the operation.

4.1.3 Clinically, according to NICE, there is strong evidence that visual acuity should not be included as part of the preoperative assessment

# 5. Summary of evidence review and references

5.1 The focus of this evidence review was to update the evidence on efficacy and safety and to recommend appropriate changes to the existing policy where appropriate.

5.2 Cataract is defined as any opacity in the crystalline lens of the eye; changes to transparency in refractive index of the lens can result in various levels of visual impairment. This impairment is associated with decreased quality-of-life because it may restrict the person's ability to carry out daily activities and function independently while increasing the risk of accidents and falls. Most commonly, cataracts affect adults as a result of biological ageing.[1]

5.3 An estimated 95 million people worldwide are affected by cataract which is one of the leading causes of blindness particularly in middle- and low-income countries. With the development of small incisional surgery, recovery is rapid with good visual outcomes and minimal complications in most patients.[2]

5.4 In 2015 – 6, over 400,000 cataract operations were performed in England and Wales.[3] By 2017/18, this had risen to 434,000 procedures at a cost of £450m per annum.[4] This is estimated to be an annual procedure rate of 4, 024 procedures per 100, 000 population aged 65 years and older. On consideration of the ageing population, it has also been suggested that the number of operations will increase by 25% over the next 10 years.[3]

5.5 Previous cataract policies set a visual acuity of 6/12 in the worst eye as a threshold for access to surgery. In addition, patients who are working in an occupation where good acuity is essential to continue their work (e.g. watchmaker) are exempt from this requirement.

5.6 Since 2004, the author has written 4 documents on cataract surgery for former Primary Care Trusts (PCTs). 1 Based on these reports, in 2003/4, the combined procedure rate for cataract surgery in Ellesmere Port and Chester PCTs was 2, 398 operations per 100, 000 population (aged 65 years and older) per annum. This was less than the then government target of 3, 200 operations per 100,000.

5.7 By 2009/10, in Western Cheshire, 3, 929 procedures per 100,000 (age 65 and over) per annum were being performed. However, this was still less than the national average of 4,150 procedures at that time. This was subsequently confirmed in 2011 by the local Standardised Admission Ratio (SAR) of 95.2 for cataracts (which adjusts for deprivation, age and gender) which indicates a lower uptake than the national average (SAR = 100).

5.8 The documents also revealed that, in 2010, the Royal College of Ophthalmologists recommended that visual acuity should not be used to gauge satisfaction – instead visual symptoms, impact on lifestyle and the patient's willingness to undergo surgery should be the driving factors. It also transpired that the available visual function questionnaires did not adequately capture quality of visual health and there was a need for a better instrument to measure the impact of surgery.

[1] Doc 1: Netcare referral pathway for cataract patients, Cheshire West and Ellesmere Port PCTs (2004), Doc 2: Developing a policy for cataract surgery, NHS Western Cheshire (2010), Doc 3: Briefing document – cataracts, costings and policy development, NHS Western Cheshire (2011) and Doc 4: Evidence review – cataract surgery, Champs (2015). ** *available from the author on request* **

5.9 The Royal College later issued a statement (2013) which underlined that visual acuity is only one part of the assessment of visual performance. Patients could experience other serious symptoms such as double vision/glare even though their visual acuity remained relatively unaffected.

5.10 The final document in this series (2015), written in conjunction with an ophthalmologist from the Royal Liverpool Hospital, concurred with the above findings and suggested that referral for cataract surgery should be based on symptomatic deterioration of vision e.g. difficulty reading, seeing TV, driving or visual disturbance e.g. glare/dazzle with bright sunlight or oncoming headlights. An example of a template using this approach was developed. It was also concluded that from a population perspective, cataract procedures are cost-effective and derive a high level of patient satisfaction.

5.11 In addition, a literature search of Medline and Embase was performed using the keywords inter alia cataract, demand management, QALY, restrict, rationalise, guideline and prioritisation. A search strategy was used, and the articles were restricted to the years 2015 – 2020 and also review articles.

5.12 Similar searches were also performed on the Cochrane database, the Scottish Intercollegiate Guidelines Network (SIGN) and NICE websites together with the NICE EVIDENCE database, Aetna (American healthcare maintenance organisation) and the Royal College of Ophthalmologists' website.

5.13 Summaries of the selected key concepts from the review articles identified during the literature search are described below.

5.14 Reports on post cataract surgery describe several parameters to measure cataract outcomes such as visual acuity, patient-reported visual function, contrast sensitivity, reading speed, residual refractive errors and operative complications. However, surgical removal of cataract is regarded as the most effective therapy known.[5] Unsurprisingly, the procedure is the most common operation performed in the UK and complication rates are less than 2%.[3] This was confirmed in the Royal College of Ophthalmologists' national audit (2019) which recorded low rates of posterior lens capsule rupture (1.2%) and visual acuity loss related to surgery (0.7%). The audit noted a 38% reduction in posterior capsule rupture since 2010.[4]

5.15 In a separate report from the USA, a review which investigated the impact of age on surgery outcomes in the very elderly (85 years and older) found that complication rates are similar to their younger counterparts. The authors concluded that their findings supported cataract surgery in this older age group.[6]

5.16 Finally, a New Zealand review article suggested that first eye cataract surgery reduces the rate of falls.[7] The same authors also confirmed that an expedited cataract surgery service (i.e. a speeded up procedure in anticipation of increasing falls risk) is very cost-effective.[8] This particular advantage (i.e. a reduction in falls) is widely recognised.[9]

5.17 From a cost utility point of view, cataract removal is considered to be highly cost-effective. A cost utility analysis written in 2017 which included 13 studies recorded a range of costs per QALY between $1307 (£1029) to $14,302 (£11,259).10 More specifically and most recently, the New Zealand data above revealed costs per QALY of £5571 for an expedited cataract surgery service and £2302 for routine cataract surgery.[7] Also, in the USA, costs per QALY were $1001 (£777) for the 1st eye and $1514 (£1175) for bilateral cataract replacement.[11]

5.18 All of these costs per QALY are well below the £20,000 maximum limit of cost effectiveness as defined by NICE.

5.19 In a review of preoperative evaluation for cataract surgery, the authors concluded that visual acuity alone is a poor gauge of cataract disability. Other options are available such as wavefront aberrometry, lens densitometry and light scatter assessment which may in the future prove to be clinically useful in surgical evaluation. However, none of these are expected to replace sound clinical judgement. [12]

5.20 Because of the large number of elderly patients presenting for cataract surgery with multiple comorbidities, there are understandable concerns about the potential for adverse events. However, a 2019 Cochrane review discovered that routine preoperative testing doesn't increase the safety of cataract surgery. The authors suggested that as an alternative, self-administered health questionnaires could substitute for provider histories and physical examinations.[13, 14]

5.21 In this context, NICE discussed the link between preoperative characteristics and outcomes and how these could be useful for both prioritisation and levels of gains expected. Owing to the lack of data, however, NICE responded by setting a research question to determine the association between preoperative vision and health-related quality-of-life, and post-operative vision related quality-of-life, health-related quality-of-life, and self-reported post-operative improvement.[1] It is not unreasonable to infer that current evidence doesn't provide a robust way of selecting patients most likely to benefit from surgery. Clearly, access to treatment should be equitable for all patients.[3]

5.22 NICE guideline NG 77 (2017) on the management of cataracts in adults explicitly states "do not restrict access to cataract surgery on the basis of visual acuity" (recommendation 1.2.2).[1] The guideline acknowledges that clinical thresholds vary across the NHS which has resulted in differences in access because policies vary in scope and content and are not necessarily consistent with research evidence or guidance provided by the Department of Health and the Royal College of ophthalmologists. NICE also state that visual acuity, although commonly used to decide whether surgery is needed, is a crude measure that will often fail to detect other vision problems which may justify surgery e.g. glare and loss of colour vision.

5.23 The full version of NG 77 15 provides a better insight into NICE's thinking on the topic of visual acuity. A thorough literature review of 10,956 references had been performed to determine the indicators for referral for cataract surgery and the optimal clinical thresholds in terms of severity and impairment for referral.

5.24 The committee noted that most prioritisation criteria are based on visual acuity and visual function questionnaire (VF 14) which captures only part of the impact of cataract and quality-of-life. It came to the conclusion that visual acuity thresholds and limits on 2nd eye surgery are likely to incur avoidable QALY losses in most cases. Because of these delays, costs could increase in the longer term by raising demand on low vision services.

5.25 Overall, no relevant studies had emerged which would inform a distinct tool or set of criteria which could be used to determine the threshold for cataract surgery. Even people rated less appropriate for surgery had small gains which were statistically significant. No studies were able to identify a group of patients by visual acuity at baseline who did not improve after surgery. The committee were, therefore, agreed it was appropriate to make a clear recommendation that visual acuity thresholds should not be used as a criterion to restrict access to cataract surgery.

5.26 NICE reaffirmed their guidance on visual acuity in their 2019 quality standard (QS 180 – 2019) in the quality statement stating "adults with cataracts are not refused surgery based on visual acuity alone."[16] The decision to treat should be based on consideration of quality-of-life and symptoms such as difficulty with reading, night driving, work or home activities, glare and loss of contrast despite optical correction. This decision should be made on the same basis for the 1st and 2nd eyes.

5.27 The Royal College of Ophthalmologists have responded to NICE guidance and reiterated the need that surgery shouldn't be restricted on the basis of visual acuity.[17] Their commissioning guide states that a number of tools to assess visual disability have been published but none of them have yet been validated for use in the UK. Further research is needed before they can be recommended for routine use. The Royal College have further observed that when commissioners use visual acuity as a threshold, this is considered to be a barrier to access.[3]

5.28 Most recently (2019), in a follow-up survey, the Royal College repeated media reports, based on a freedom of information request, that 53% of CCGs in England are restricting access in this way.[18] It is the College's view that where guidance is being ignored, patients are not receiving equitable care based on the best evidence on clinical and cost effectiveness.

5.29 In summary:

- 5.29.1 Cataracts can have a significant impact on quality of life and are extremely common in older people. Because of this demography, the prevalence is rising.
- 5.29.2 During the 1st decade of 2000, the surgical procedure rate in western Cheshire has consistently been less than the national average. This could indicate an unmet need.
- 5.29.3 Adverse events or complication rates aren't raised in the very elderly (85 years and older) and there has been an overall decrease in these since 2010.
- 5.29.4 Various cost utility analyses have consistently demonstrated that the costs per QALY are well below NICE's maximum limit of cost effectiveness. This is irrespective of 1st eye, 2nd eye or age and the procedure is still considered to be cost-effective even in those least likely to benefit.
- 5.29.5 Currently, there is no validated pre-and/or post assessment tool to determine which cohort (if any) are most likely to derive benefit from the operation.
- 5.29.6 Clinically, there is strong evidence that visual acuity should not be included as part of the preoperative assessment.

5.30 In conclusion:

- 5.30.1 It is clinically inappropriate to use visual acuity as a referral criterion and this should be removed from the Cheshire CCG policy.
- 5.30.2 Referrals for cataract surgery should be based on deteriorating vision, quality-of-life, fitness for surgery and consent. A local assessment tool has been developed for this purpose.

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# 6. Advice and Guidance

## 6.1 **Aim and Objectives**

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

### 6.2 Core Principles

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:
  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
  - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
  - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
  - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
  - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
  - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
  - Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

### 6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.
- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

### 6.4 Cosmetic Surgery

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.
- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.
- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

### 6.5 Diagnostic Procedures

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 **Clinical Trials**

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

# 7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

# 8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

# 9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**
C71 C72 C74 C75

9.2 **International classification of diseases (ICD-10)**
H280 Q120 H25 H26

# Document Control

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