NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Age-Related Macular Degeneration (AMD), implantable miniature telescope (IMT)

Category 1 Intervention - Not routinely commissioned -

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Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
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Document control:		
Date:	**Version Number:**	**Section and Description of Change**
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1. Introduction

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

1.2 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 in Appendix 1.

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

2. Purpose

2.1 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.

3. Policy statement

3.1 The implantable miniature telescope (IMT) in the treatment of advanced age-related macular degeneration (AMD) is not routinely commissioned.

4. Exclusions

4.1 None

5. Rationale

5.1 Owing to the limited amount of data on safety and effectiveness, lack of inter-person controls and the crucial need for highly selected patients, it is concluded that the implantable miniature telescope should be regarded as experimental until further research is published.

6. Underpinning evidence

6.1 Age-related macular degeneration (AMD) is an age associated disease which causes progressive and irreversible damage to the central part of the retina i.e. macula. AMD has two forms, described as wet (amenable to treatment by anti-VEGF drugs) and the much more common type of dry (non-neovascular). [1] AMD is the most common cause of visual impairment in the developed world and the prevalence is 4.8% in people aged 65 years or older and 12.2% in those aged 80 years or over. [2]

6.2 The implantable miniature telescope (IMT) is an ophthalmic device which works in conjunction with the cornea to improve near and distance vision in individuals who have lost bilateral central vision due to wet or dry end stage AMD. Once implanted, the telescope enlarges objects in the person's central visual field and focuses them onto healthy areas of the retina unaffected by AMD which permits individuals to recognise objects which previously they couldn't see. The telescope is implanted into one eye only and this eliminates peripheral vision in the implanted eye. As a result, the individual must rely solely on the non-implanted eye for their peripheral vision after surgery. Unsurprisingly, perhaps, all recipients must

undergo rehabilitation to learn how to adjust to the device. The IMT will not restore vision to pre-AMD levels, it may, however, increase independence and reliance on caregivers.[1]

6.3 The current Cheshire CCG policy is to not routinely commission the IMT, known commercially as VisionCare™. The underpinning evidence consists of 2 references, the first referring to a North-East Treatment Advisory Group review on the topic, published in 2012 which stated that the approximate cost at that time was £13,000 per person. [3] The second, refers to NICE, Interventional Procedure Guidance IPG 272, nominally published in 2008, but this guidance has since been withdrawn. As a result, a rapid review of the literature was performed limited to the last 5 years.

6.4 IPG 272 has been replaced by IPG 565 which is interventional procedures guidance on the miniature lens system for AMD, published in 2016.[4] This guidance suggests there is currently insufficient long-term evidence on both efficacy and safety and so special arrangements are required for clinicians wishing to carry out this procedure. Patients must be told about the risk of early complications and uncertainties regarding the long-term efficacy and safety. In addition, careful patient selection and assessment should predict the patient's ability to cope with the changes in vision after the operation (see above). It is worth noting that the advisory committee reported good outcomes in some patients but difficulties in others who were unable to cope with the high magnification images.

6.5 In subsequent publications, Grzybowski (2017) reviewed 7 types of intraocular lenses for AMD and suggested no single ideal lens is available without drawbacks. [5] The main problems encountered were the strict patient selection criteria required and that further independent clinical studies with longer follow-up data were necessary prior to the general use of these devices. In an updated review (2020), Grzybowski reviewed 4 types of intraocular lens, which included the IMT, and concluded that more extensive, randomised and long duration follow-up clinical trials were still required to evaluate safety and efficacy. [6]

6.6 Finally, in 2018, a Cochrane review of the IMT for vision loss due to end-stage AMD assessed its effectiveness and safety in improving visual acuity and quality-of-life. [1] Owing to the lack of data, the authors were unable to draw any conclusions about the effectiveness and safety of the IMT. There was a clear need for studies to be conducted which compare IMT–implanted patients to those with no implant; all previous studies have included implanted patients who acted as their own internal controls.

6.7 Owing to the limited amount of data on safety and effectiveness, lack of inter-person controls and the crucial need for highly selected patients, it is concluded that the implantable miniature telescope should be regarded as experimental until further research is published. The "not routinely commissioned" policy should be maintained, and this is consistent with the policy from Mersey CCG.

REFERENCES

1. Gupta A, Lam J, Custis P, et al. Implantable miniature telescope (IMT) for vision loss due to end-stage age-related macular degeneration. *Cochrane Database of Systematic Reviews* 2018(5) doi: 10.1002/14651858.CD011140.pub2
2. Age-related macular degeneration. Nice guideline. London: National Institute for health and care excellence, 2018:NG 82.
3. Horsley W. Intraocular telescope by VisionCare for age-related macular degeneration. Newcastle: North East treatment advisory group, 2012:12.
4. Miniature lens system implantation for advanced age related macular degeneration. Interventional procedures guidance. London: National Institute for health and care excellence, 2016:IPG 565

5. Grzybowski A, Wasinska-Borowiec W, Alio JL, et al. Intraocular lenses in age-related macular degeneration. *Graefe's archive for clinical and experimental ophthalmology = Albrecht von Graefes Archiv fur klinische und experimentelle Ophthalmologie* 2017;**255**(9):1687-96. doi: 10.1007/s00417-017-3740-8
6. Grzybowski A, Wang J, Mao F, et al. Intraocular vision-improving devices in age-related macular degeneration. *Annals of translational medicine* 2020;**8**(22):1549. doi: 10.21037/atm-20-5851

7. Force

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.

8. Coding

8.1 **Office of Population Censuses and Surveys (OPCS)**

C75.1 Insertion of prosthetic replacement for lens NEC

8.2 **International classification of diseases (ICD-10)**

H35.3 Degeneration of macula and posterior pole

9. Monitoring And Review

9.1 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

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

10. Quality and Equality Analysis

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

Appendix 1 - Core Objectives and Principles

Objectives

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.

Principles

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.

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.

Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

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 wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

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

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.

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.

Clinical Exceptionality

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.