

Clinical Commissioning Policy

Visual stress and reading difficulties treatment using coloured filters or lenses.

Category 1 Intervention - Not routinely commissioned -

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| Version: | 1 |
| 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. |
| Supersedes: | Previous Clinical Commissioning Group (CCG) Policy |
| Author (inc Job Title): | |
| Ratified by: (Name of responsible Committee) | ICB Board |
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| Target audience: | All Cheshire & Merseyside ICB Staff and Provider organisations |

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| Document control: | | |
|--------------------------|------------------------|--|
| Date: | Version Number: | Section and Description of Change |
| April 2023 | 1 | Policy ratified by Cheshire & Merseyside ICB |
| June 2024 | 2 | Title and statement amended following review and consultation. Indications have been broadened in light of published literature. |
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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 Coloured filters, lenses or overlays (including Irlen) are not routinely commissioned in the management of visual stress or individuals with reading difficulties.

4. Exclusions

- 4.1 None

5. Rationale

- 5.1 Coloured filters, lenses or overlays (including those made by Irlen) in the management of visual stress or people with reading difficulties are not routinely commissioned because the published evidence to support this is limited.

6. Underpinning evidence

- 6.1 Reading disability affects up to 18% of school-age children in the UK. If left untreated, it can adversely affect emotional, behavioural and socio-economic outcomes in adulthood.¹ Dyslexia is a neurodevelopmental disorder which is characterised by slow and inaccurate word recognition which causes difficulties with accurate and/or fluent word recognition and spelling. Learning difficulties associated with dyslexia may be caused by:
 - a. visual problems through not being able to recognise shape and form,
 - b. reading speed, accuracy or comprehension,
 - c. phoneme¹ segmentation (cannot see or hear the components and then put them together to create meaning and to spell the words).It has been estimated that up to 10% of the UK population has some degree of dyslexia.

- 6.2 In 1983, Irlen described scotopic sensitivity syndrome (also known as visual stress or Meares-Irlen syndrome) which was said to cause visual discomfort in a subgroup of people with dyslexia.² The syndrome was diagnosed with the Irlen differential perceptual schedule (IDPS) test and the proposed perceptual disorder is said to cause an individual to experience visual distortions and illusions when viewing text, and interferes with reading ability. Individually prescribed coloured filters, either tinted spectacle lenses or coloured sheets of plastic (overlays) are also said to alleviate these visual distortions, removing an obstacle to reading instruction.
- 6.3 The current Cheshire CCG “not routinely commissioned” policy on coloured filters in the treatment of dyslexia is based on a single article (2008) which was a systematic review of the effectiveness and cost effectiveness of coloured filters for reading disability written by the West Midlands Health Technology Assessment Collaboration in the University of Birmingham.¹ This extremely comprehensive review concluded that its meta-analysis and qualitative assessment did not show that coloured filters led to a clear improvement in reading ability in subjects with reading disability. It was not possible to comment on whether these filters could improve symptoms of visual stress that may be associated with reading disability due to a lack of available evidence. Further, based on the evidence, the review team concluded there can be no major implications for current practice in the treatment of reading disability. Further well-designed research may generate clearer results. The Cheshire CCG policy also states that this intervention is not routinely commissioned until such time as when there is robust evidence.
- 6.4 Therefore, in order to identify such evidence, a rapid review of articles published within the last 10 years was performed. In 2011, a study of 61 schoolchildren with reading difficulties tested the efficacy of Irlen coloured overlays for alleviating these problems. The study found no evidence of benefit as measured by the reading rate test or global reading measure and concluded that the overlays didn’t have a demonstrable immediate effect on reading in children with reading difficulties.²
- 6.5 Five years later, a systematic review(2016) of the literature on coloured lenses and overlays to improve reading performance identified 51 published items. The majority of studies were subject to high or uncertain bias and the effect sizes were generally small or similar to placebo. The authors concluded that use of coloured lenses or overlays to ameliorate reading difficulties cannot be endorsed and any benefit in clinical settings are likely to be the result of placebo or the Hawthorne effect.³
- 6.6 In 2019, a systematic review of the Irlen syndrome obtained evidence on the aetiology, diagnosis and effectiveness of treatment. The data showed high heterogeneity among studies, and lack of evidence on the existence of the “Irlen syndrome” and treatment effectiveness. The authors concluded that further strong evidence was required regarding the syndrome itself as well as its treatments.⁴
- 6.7 Aetna, the American healthcare maintenance organisation, in its policy² on learning disabilities, dyslexia and vision considers the use of coloured filtered/tinted lenses as experimental and investigational for the treatment of dyslexia or learning disabilities because the effectiveness for these indications has not been established. Perhaps, the most damning indictment of this intervention is provided in a personal opinion written by an ophthalmologist in the British Medical Journal. The article discusses Irlen syndrome which is promoted by the Irlen Institute based in California. It alleges that the Institute “sells expensive lenses to people with vague collections of symptoms and concludes that the medical profession must be united in its stand against pseudoscientific nonsense such as Irlen syndrome”.⁵
- 6.8 It is concluded that no new positive evidence in favour of in the treatment of dyslexia has been published since 2008. It is therefore recommended that the policy of not routinely

commissioned should be maintained. This stance will maintain consistency with the current Mersey CCG policy.

REFERENCES

1. Albon E, Adi, Y., Hyde, C. The effectiveness and cost effectiveness of coloured filters for reading disability: a systematic review. A West Midlands health technology assessment collaboration report. Birmingham: Department of Public health and epidemiology, West Midlands health technology assessment group, 2008:123.
2. Ritchie SJ, Sala SD, McIntosh RD. Irlen Colored Overlays Do not Alleviate Reading Difficulties. *Pediatrics* 2011;**128**(4):e932. doi: 10.1542/peds.2011-0314
3. Griffiths PG, Taylor RH, Henderson LM, et al. The effect of coloured overlays and lenses on reading: a systematic review of the literature. *Ophthalmic Physiol Opt* 2016;**36**(5):519-44. doi: 10.1111/opo.12316 [published Online First: 2016/09/02]
4. Miyasaka JDS, Vieira RVG, Novalo-Goto ES, et al. Irlen syndrome: systematic review and level of evidence analysis. *Arq Neuropsiquiatr* 2019;**77**(3):194-207. doi: 10.1590/0004-282x20190014 [published Online First: 2019/04/11]
5. Williams GS. Irlen syndrome: expensive lenses for this ill defined syndrome exploit patients. *Bmj* 2014;**349**:g4872. doi: 10.1136/bmj.g4872 [published Online First: 2014/09/23]

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)

None

8.2 International classification of diseases (ICD-10)

F81.0 Specific reading disorder

R48.0 Dyslexia and alexia

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/Optommetrist/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/Optommetrist/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.