NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Surgical management of children (younger than 12 years) with Otitis Media with Effusion (OME)

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

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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**
April 2023	1	Policy ratified by Cheshire & Merseyside ICB
April 2026	2	Policy ratified at Clinical Effectiveness Group

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. Summary of intervention

3.1 This is a surgical procedure to insert tiny tubes (grommets or tympanostomy tubes) into the eardrum as a treatment for fluid build-up (glue ear) when it is affecting hearing in children.

3.2 Glue ear is a very common childhood problem (4 out of 5 children will have had an episode by age 10), and in most cases it clears up without treatment within a few weeks. Common symptoms can include earache and a reduction in hearing.

3.3 In some cases, the hearing loss can cause language, educational and behavioural problems and may impact on daily living. In these circumstances, insertion of grommets can be a useful intervention.

4. Policy statement

4.1 **Essential prerequisite and general management of otitis media with effusion** - It is assumed that the general management of these children in terms of information and advice, recognition and assessment, reassessment, non-surgical management, otorrhoea, infection and follow up are all in accordance with NICE guideline NG 233 “Otitis media with effusion in under 12s” and any other relevant NICE guidance such as NG 91, “Otitis media (acute): antimicrobial prescribing”.

4.2 Surgical intervention should be given equal consideration as management of hearing loss (i.e. hearing aids).

4.3 Surgical management (insertion of grommets or tympanostomy tubes) is routinely commissioned if the following criteria are satisfied:-

4.3.1 In a child with 3 months of bilateral (i.e. in both ears) hearing loss **OR**

4.3.2 In a child with 3 months of unilateral i.e. (one ear) hearing loss which is impacting on daily living or communication **OR**

4.3.3 In a child with unilateral or bilateral hearing loss which is impacting on daily living or communication before the 3 months' assessment **AND**

4.3.4 **In all cases** (4.3.1 – 4.3.3 above), the benefits and harms of choosing either grommet surgery and hearing aids were fully discussed and a shared decision made to proceed by the clinician, child and their parents or guardians.

4.4 Unless contra-indicated, adenoidectomy is routinely commissioned when **all of** the following criteria are satisfied:-

4.4.1 The child is listed for surgical insertion of grommets **AND**

4.4.2 Adenoidectomy will be performed during the grommet insertion procedure **AND**

4.4.3 The benefits and harms of adjuvant adenoidectomy were fully discussed and a shared decision made to proceed by the clinician, child and their parents or guardians

5. Exclusions

5.1 The following conditions are considered outside the scope of this policy and thus are excluded:-

- Suspected cholesteatoma.
- Chronic suppurative otitis media.
- Adenoidectomy performed for indications not related to OME (e.g. sleep apnoea, chronic rhinosinusitis, nasal obstruction, speech surgery in cleft palate).
- Retraction of the ear drum without effusion.

6. Rationale

6.1 Glue ear (otitis media with effusion) is a very common childhood problem and the majority of cases will clear up without treatment within a few weeks.

6.2 Surgical intervention (i.e. insertion of grommets) is only necessary when any associated hearing loss is having a significant impact on daily activity or is likely to do so in the future if left untreated.

6.3 Surgery is not without its risks and, therefore, the decision to proceed is a joint one between the parents/guardians and surgeon after all the potential risks and benefits and other options have been discussed.

6.4 The policy statements are based on recommendations from NICE guidance and also advice from local experts in the field.

7. Underpinning evidence

7.1 Otitis media with effusion (OME) or glue ear in children is extremely common and in the majority of cases the problem is transient and will disappear of its own accord. However, in a relatively small number of cases where OME persists, the development of hearing loss is a distinct possibility. If this is left unchecked, these children may then go on to experience educational, speech, language, communication and behavioural problems or even long-term hearing loss.

7.2 Current treatment policies are driven by the former NICE guideline CG 60 which was first published in 2008 and subsequently supported by the EBI programme (2018).[1] Of the literature published since 2018, there is continued support for grommet insertion in

children with bilateral OME and hearing loss. A watchful waiting period of 3 months before surgery seems to be a consistent requirement throughout.

7.3 Adenoidectomy has received a lot of attention and is broadly recommended as an option when conducted at the same time as surgery for grommet insertion i.e. when the patient is already scheduled for a general anaesthetic. The likelihood is that adenoidectomy helps to reduce OME which in turn will address problems with hearing loss. However, this is based on limited evidence. Whether adenoidectomy alone or in conjunction with grommet surgery is beneficial is still open to debate.

7.4 Whilst grommet surgery is appropriate in children with OME and hearing loss after a 3 months' waiting period, there may be some children who may be experiencing significant functional difficulties during this period to the extent that earlier surgical intervention may be warranted.

7.5 The 2023 NICE guideline (NG 233) [2] continues to recommend a 3 months' waiting period and surgery is considered to be appropriate in those with a hearing deficit, but unlike the previous version (CG 60), NICE do not specify the level of hearing loss. This applies to children with bilateral hearing loss and unilateral hearing loss which is impacting on daily activity. In addition, any child (unilateral or bilateral hearing loss) may be eligible for surgery *before* the waiting period if they are also experiencing an impact on daily activity or communication. *Crucially*, NICE have now designated hearing aids as an equivalent option to surgery and are now more relaxed towards adjuvant adenoidectomy.

7.6 Finally, despite its recommendations in NG 233, NICE specified research recommendations to examine the clinical and cost-effectiveness of both hearing aids and grommet insertion. In addition, a more in-depth literature review (available on request) located two Cochrane reviews which assessed the benefits/harms of adenoidectomy alone or in combination with grommets [3] and the benefits and harms of ventilation tubes alone. [4] Both of these concluded that the evidence is uncertain and more research is required.

7.7 It is a fair observation that, perhaps, the underpinning evidence may not be as robust as possible and that additional research is still required. However, the literature review hasn't revealed any new information published since 2018 which would compromise the recommendations made in NG 233. The overall conclusion is that development of policies for management of OME should be based on NG 233 until further research comes to light.

REFERENCES

1. Evidence-based interventions: guidance for CCGs. *Evidence-based interventions: guidance for CCGs: List 1* 2018 (updated 2019);NHS England:180.
2. Otitis media with effusion in under 12s. *NICE guideline* 2023;**NG 233**;National institute for health and care excellence (NICE):NG 233.
3. MacKeith S, Mulvaney CA, Galbraith K, et al. Adenoidectomy for otitis media with effusion (OME) in children. *Cochrane Database of Systematic Reviews* 2023(10) doi: 10.1002/14651858.CD015252.pub2
4. MacKeith S, Mulvaney CA, Galbraith K, et al. Ventilation tubes (grommets) for otitis media with effusion (OME) in children. *Cochrane Database of Systematic Reviews* 2023(11) doi: 10.1002/14651858.CD015215.pub2

8 Force

8.1 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.

9 Coding

SQL code

```
WHEN left(der.Spell_Dominant_Procedure,4) IN ('D151','D289')
AND (der.Spell_Primary_Diagnosis like 'H65[23]%' OR der.Spell_Primary_Diagnosis like
'H66[1-9]%')
AND (ISNULL(APCS.Age_At_Start_of_Spell_SUS,APCS.Der_Age_at_CDS_Activity_Date)
between 0 AND 18 OR
ISNULL(APCS.Age_At_Start_of_Spell_SUS,APCS.Der_Age_at_CDS_Activity_Date)
between 7001 AND 7007 )
AND APCS.Admission_Method not like ('2%')
THEN 'G_gromm'
```

Global cancer exclusion

```
APC
WHERE 1=1
-- Cancer Diagnosis Exclusion
AND (apcs.der_diagnosis_all not like '%C[0-9][0-9]%'
AND apcs.der_diagnosis_all not like '%D0%'
AND apcs.der_diagnosis_all not like '%D3[789]%'
AND apcs.der_diagnosis_all not like '%D4[012345678]%'
OR apcs.der_diagnosis_all IS NULL)
```

10 Monitoring And Review

10.1 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 notes audits

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

11 Quality and Equality Analysis

11.1 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.