NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Grommets for glue ear in children

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**
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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.

1.4 This policy is based on NHS England's Evidence-Based Interventions (EBI) recommendations see link to programme below - accurate at the point of publication https://www.aomrc.org.uk/ebi/clinicians/grommets-for-glue-ear-in-children/.

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) 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 Often, when the hearing loss is affecting both ears it can cause language, educational and behavioural problems.

4. Policy statement

4.1 Insertion of grommets (ventilation tubes) in the treatment of glue ear in children is routinely commissioned when the criteria set out by the NICE guidelines are met:

4.1.1 All children must have had specialist audiology and ENT assessment.

4.1.2 Persistent bilateral otitis media with effusion over a period of 3 months.

4.1.3 Hearing level in the better ear of 25-30dbHL or worse averaged at 0.5, 1, 2, & 4kHz

4.1.4 Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25-30dbHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.

4.1.5 Healthcare professionals should also consider surgical intervention in children who cannot undergo standard assessment of hearing thresholds where there is clinical and tympanographic evidence of persistent glue ear and where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.

4.1.6 The guidance is different for children with Down's Syndrome and Cleft Palate, these children may be offered grommets after a specialist MDT assessment in line with NICE guidance.

4.1.7 It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed, with tympanometry as a minimum.

4.2 The risks to surgery are generally low, but the most common is persistent ear discharge (10-20%) and this can require treatment with antibiotic eardrops and water precautions. In rare cases (1-2%) a persistent hole in the eardrum may remain, and if this causes problems with recurrent infection, surgical repair may be required (however this is not normally done until around 8-10 years of age).

5. Exclusions

5.1 This guidance only relates to children with Glue Ear (Otitis Media with Effusion) and SHOULD NOT be applied to other clinical conditions where grommet insertion should continue to be normally funded, these include:

- Recurrent acute otitis media
- Atrophic tympanic membranes
- Access to middle ear for transtympanic instillation of medication Investigation of unilateral glue ear in adults.

6. Rationale

6.1 In most cases glue ear will improve by itself without surgery. During a period of monitoring of the condition a balloon device (e.g. Otovent) can be used by the child if tolerated, this is designed to improve the function of the ventilation tube that connects the ear to the nose. In children with persistent glue ear, a hearing aid is another suitable alternative to surgery. Evidence suggests that grommets only offer a short-term hearing improvement in children with no other serious medical problems or disabilities.

6.2 The NHS should only commission this surgery when the NICE criteria are met, as performing the surgery outside of these criteria is unlikely to derive any clinical benefit.

7. Underpinning evidence

7.1 NICE guidance (2008): Otitis media with effusion in under 12s: surgery [CG60]

7.2 Browning, G; Rovers, M; Williamson, I; Lous, J; Burton, MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. Cochrane Database of Systematic Reviews 2010, Issue 10. Art. No.: CD001801. doi: 10.1002/14651858.CD001801.pub3

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 note 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.