Derby and Derbyshire
Integrated Care Board

CLINICAL POLICY ADVISORY GROUP (CPAG)

Grommets in Otitis Media with Effusion Policy

Statement

NHS Derby and Derbyshire ICB (DDICB), in line with its principles for Evidence Based Interventions (EBI, has deemed grommets should not be routinely commissioned for children and adults unless the criteria in this policy are met:

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

1. Background

Otitis media with effusion (OME) is a condition characterized by a collection of fluid within the middle ear space without signs of acute inflammation. OME can be associated with significant hearing loss, especially if it is bilateral and lasts for longer than one month. Often, when the hearing loss is affecting both ears it can cause language, educational and behavioural problems.

The exact cause of OME is uncertain, but over 50% of cases are thought to follow an episode of acute otitis media (AOM), especially in children under 3 years of age. Persistent OME can occur because of the following:

- Impaired eustachian tube function causing poor aeration of the middle ear.
- Low-grade viral or bacterial infection.
- Persistent local inflammatory reaction.
- Adenoidal infection or hypertrophy

Grommets is a surgical procedure to insert tiny tubes (grommets) into the eardrum as a treatment for fluid build-up (glue ear).

2. Recommendation

Recommendation for Children

The commissioner will fund grommets in children, who are over the age of two and under 12 years of age who have bilateral OME which is having an impact on the child's hearing, that persists after a period of at least three months of watchful waiting from the date that the problem was first identified by the GP to the date of referral. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter' in those children thought to tolerate the procedure (usually at least 3 years old). If these do not improve symptoms, children can be referred if they have one of the following:

- There have been at least 5 recurrences of AOM, which required medical assessment and/or treatment in the last 12 months.
- There is hearing loss of at least 25-30dB in the better ear. (Pure tone audiometry findings averaged across all four tones)
- There is evidence of delay in speech development, educational or behavioural problems attributable to the hearing loss or a significant second disability that may itself lead to developmental problems, e.g., Down's syndrome, Turner's syndrome of a cleft palate
- Assessment and reassessment indicate that there is unilateral hearing loss if hearing is impacting daily living or communication
- It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed, with tympanometry

Adjuvant adenoidectomy

When planning grommet surgery for the management of glue ear, consider adjuvant adenoidectomy unless assessment indicates an abnormality with the palate.

Adjuvant adenoidectomy for the treatment of glue ear can be considered if:

- The child is undergoing grommet surgery for treatment of hearing loss due to glue ear.
- The child is undergoing surgery for re-insertion of grommets due to recurrence of previously surgically treated glue ear.

The benefits and risks of adenoidectomy has been discussed with the child and their family or carers, and a shared decision has been made on whether to have the procedure. Including that there is a risk of haemorrhage, and velopharyngeal insufficiency
This guidance only refers to children undergoing adenoidectomy for the treatment of glue ear and should not be applied to other conditions where adenoidectomy should continue to be routinely funded:

- As part of treatment for obstructive sleep apnoea or sleep disordered breathing in children (e.g. as part of adenotonsillectomy).
- As part of the treatment of chronic rhinosinusitis in children.
- For persistent nasal obstruction in children and adults with adenoidal hypertrophy.
- In preparation for speech surgery in conjunction with the cleft surgery team.

Recommendation for Adults

The commissioner will fund grommets in adults with OME if at least one of the following criteria is met:

- A period of 3 months of watchful waiting prior to referral. Significant negative middle ear pressure measured on two sequential appointments, with no resolution within 3 months of first presentation. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter'. If these do not improve symptoms, hearing aids should be the next intervention offered prior to further treatment.
- Repetitive AOM (3 episodes in 6 months or 4 in 12 months) when it does not respond to ongoing antibiotic therapy and impairs speech, hearing or both.
- Barotrauma (persistent Eustachian tube dysfunction): Damage from changes in pressure, such as scuba diving or flying, causing pain.
- Unilateral middle ear effusion where a post-nasal space examination and/or biopsy is required to exclude underlying malignancy.

Exclusion Criteria: The Grommets Policy only applies to patients with OME. This policy does not apply to conditions such as Meniere's Disease/existence of retraction pockets and the insertion of grommets in these conditions.

3. Rationale for Recommendation

In most cases OME 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. Evidence suggests that grommets only offer short-term hearing improvement in children with no other serious medical problems or disabilities. In situations where OME is not having an impact on the child's hearing, there is no urgent need to consider surgery, regardless of whether the OME is persistent or transient, in light of the risks associated with grommet insertion. Use a shared decision approach to discuss the benefits and risks of grommets with the child and their parents and carers, cover that there is a risk of perforation of the eardrum, atelectasis, tympanosclerosis and infection associated with grommets.

NICE guidance recommends that adjuvant adenoidectomy can be considered when planning grommet surgery. The most important outcome in children with glue ear for measuring the effectiveness of an intervention is the improvement in hearing. There is some evidence that adenoidectomy with or without unilateral or bilateral grommets reduced the presence or persistence of glue ear. Experts agree that if adenoidectomy improves the glue ear, it may also have beneficial effects on hearing.

Adjuvant adenoidectomy is considered a low-risk procedure and if someone is already having general anaesthesia for grommets, the added risk of doing adenoidectomy at the same time is likely to be very small.

Risks include the increased length of surgery, damage to teeth, lips or gums, bleeding (usually only minor and self-resolving), and rarely (around 1%) velopharyngeal insufficiency (VPI). VPI can result in speech problems such as hypernasal speech or audible escape of air out of the nose when talking and in some cases can cause nasal regurgitation.

In those with an abnormality of the palate, adenoidectomy is likely to lead to velopharyngeal insufficiency or nasal regurgitation, and so this procedure is not likely to be appropriate for this group.

4. Personalised Care

Personalised care simply means that people have more control and choice when it comes to the way their care is planned and delivered, considering their individual needs, preferences and circumstances. It includes supporting shared decision making and self-management.
Shared decision-making means people are supported to:

- *understand the care, treatment and support options available and the risks, benefits and consequences of those options*
- *decide on a preferred course of action, based on evidence based, good quality information and their personal preferences.*

Supported self-management means increasing the knowledge, skills and confidence a person has in managing their own health and care. This involves using self-management education, peer support, and health coaching.
Decision support tools, also called patient decision aids support shared decision making by making treatment, care and support options explicit. They provide evidence-based information about the associated benefits/harms and help patients to consider what matters most to them in relation to the possible outcomes, including doing nothing.

5. Useful Resources

- NHS Website. Glue Ear. https://www.nhs.uk/conditions/glue-ear/
- NHS England » Decision support tool: making a decision about glue ear if your child has hearing loss

6. References

- Evidence Based Interventions. Academy of Medical Royal Colleges. https://ebi.aomrc.org.uk/interventions/grommets-for-glue-ear-in-children/
- Evidence Based Interventions. Academy of Medical Royal Colleges https://ebi.aomrc.org.uk/interventions/removal-of-adenoids-for-treatment-of-glue-ear/
- NICE Clinical Guideline (NG233): Otis Media with Effusion in Under 12s. Published August 2023. http://www.nice.org.uk/guidance/ng233NICE CKS Otis Media with Effusion, Updated 2021. https://cks.nice.org.uk/topics/otitis-media-with-effusion/
- NICE guideline NG233 Evidence Review [F] (2023) Otitis media with effusion in under 12s [F] Evidence reviews for adenoidectomy for children with otitis media with effusion (OME). https://www.nice.org.uk/guidance/ng233/evidence/f-adenoidectomy-for-children-with-ome-pdf-13133198707
- Royal College of Surgeons/ ENT UK (2013) Commissioning Guide: Otitis Media with

Effusion https://www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/otitis-media-guide/
- Bedfordshire and Hertfordshire CCGs. https://prioritiesforum.org.uk/sites/default/files/policies/ 2019-03/guidance_72_-_grommets_in_adults_september_2018.pdf
- MacKeith S, Mulvaney CA, Galbraith K, Webster KE, Paing A, Connolly R, Marom T, Daniel M, Venekamp RP, Schilder AGM. Adenoidectomy for otitis media with effusion (OME) in children. Cochrane Database of Systematic Reviews 2023, Issue 10. Art. No.: CD015252. DOI: 10.1002/14651858.CD015252.pub2 https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015252.pub2/full
- Rosenfeld RM, Shin JJ, Schwartz SR, et al. Clinical practice guideline: Otitis media with effusion executive summary (update). Otolaryngol Head Neck Surg. 2016;154(2):201-214. doi: 10.1177/0194599815624407.

7. Appendices

Appendix 1 - Consultation

All relevant providers/stakeholders will be consulted via a named link consultant/specialist. Views expressed should be representative of the provider/stakeholder organisation. CPAG will consider all views to inform a consensus decision, noting that sometimes individual views and opinions will differ.

Consultee	**Date**
Clinical Policy Advisory Group (CPAG)	November 2024
Consultant ENT Surgeon, CRHFT	November 2024
ENT and Facial Plastics Consultant, CRHFT	November 2024
Consultant ENT Surgeon, UHDBFT	November 2024
Consultant Oral & Maxillofacial Surgeon, UHDBFT	November 2024
Clinical Policy Advisory Group (CPAG)	January 2025

Appendix 2 - Document Update

Document Update	**Date Updated**

Version 6.0
• Adoption of updated EBI guidance for Removal of Adenoids for Glue Ear
• Following additional criteria added:
  ○ Unilateral hearing loss if hearing is impacting daily living or communication
  ○ Children aged under 12
  ○ It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed, with tympanometry
• Addition of 'Personalised Care' section
	January 2025