

CLINICAL POLICY ADVISORY GROUP (CPAG)

Grommets in Otitis Media with Effusion Policy

This procedure requires prior approval. Prior approval must be sought through Blueteq.

Criteria

■ Black – criteria required to be met prior to referral

■ Blue – criteria to be met prior to procedure

Statement

Derby and Derbyshire CCG, in line with its principles for procedures of limited clinical value, has deemed grommets should be commissioned for children and adults when the following criteria is met:

- **Children** - over the age of two, who have bilateral otitis media with effusion (OME) 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 meet one of the following criteria:
 - There have been at least 5 recurrences of acute otitis media, which required medical assessment and/or treatment in the last 12 months. In cases of recurrent OME, adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.
 - 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 (such as Down's syndrome, Turner's syndrome or a cleft palate).
- **Adults** - with OME if at least one of the following criteria are 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 acute otitis media (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.

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

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.

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.

2. Recommendation

Recommendation for Children

Grommets will be funded for children, who are over the age of two, who have bilateral OME 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.
 - In cases of recurrent OME, adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.
- 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 behavioral 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 or a cleft palate.

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 do not require prior approval.

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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.

4. Useful Resources

- NHS England Evidence-Based Interventions: Guidance for CCGs, first published 2018, updated January 2019.
- NICE Clinical Guideline (CG60): Otitis Media with Effusion in Under 12s: Surgery, Published February 2008, <https://www.nice.org.uk/guidance/cg60/resources/otitis-media-with-effusion-in-under-12s-surgery-pdf-975561238213>

5. References

- Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ (2010) 'Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children.' Cochrane Database of Systematic Reviews 2010, Issue 10.
- National Institute of Health and Care Excellence (2008) [National Collaborating Centre for Women's and Children's Health (NCC-WCH).] Clinical Guideline 60: Surgical management of otitis media with effusion in children. London: RCOG Press; 2008.
- Royal College of Surgeons/ ENT UK (2013) Commissioning Guide: Otitis Media with Effusion
- Van den Ardbeg MTA, Schiller AGM, Herbert E, Biohacker CWB, Rovers MM (2010)
- 'Adenoidectomy for otitis media in children.' Cochrane Database of Systematic Reviews 2010, Issue 1.
- NHS England Evidence-Based Interventions: Guidance for CCGs, first published 2018, updated January 2019.
- NICE CKS Otitis Media with Effusion, last updated October 2016, <https://cks.nice.org.uk/otitis-media-with-effusion#!topicSummary>
- NICE Clinical Guideline (CG60): Otitis Media with Effusion in Under 12s: Surgery,

6. Appendices

Appendix 1- Consultation

Consultee	Date
Consultant ENT Surgeon, UHDB	August 2019
Consultant ENT Surgeon, CRHFT	August 2019
Clinical Policy Advisory Group	August 2019
Clinical and Lay Commissioning Committee	September 2019
Clinical Policy Advisory Group	October 2019
Clinical and Lay Commissioning Committee	November 2019

Appendix 2- Document Update

Document Update	Date Updated
Policy updated – version 3	December 2016
Policy updated – version 3.1	March 2017
Policy updated – version 3.1	November 2017
Policy updated – version 4	August 2019
Policy updated – version 4.1 (addition of Exclusion Criteria and the statement ‘This procedure requires prior approval. Prior approval must be sought through Blueteq.’, as requested by contracting)	October 2019
Policy updated – version 4.2 (Clarification that the policy only applies to grommets in Otitis Media with Effusion, and conditions such as Meniere’s disease/ existence of retraction pockets do not require prior approval and policy name updated to ‘ Grommets in Otitis Media with Effusion Policy’ instead of ‘Grommets Policy’)	November 2019