

THRESHOLD POLICY – T7b GROMMETS IN ADULTS

Policy author:	Ipswich and East and West Suffolk CCG with support from Public Health Suffolk.
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Previous review dates	September 2014 February 2017
Next review date:	February 2020

1. Policy Summary

- 1.1 This policy does not apply to anyone under 19 years of age. For the use of grommets in children, please see policy T7a.

2. Eligibility Criteria

- 2.1 IES and WS CCGs will **only** fund grommet insertion **in adults** (aged 19 and over) when the following criteria are met:
- a) Insertion of grommets as part of a more extensive surgical procedure **or**
 - b) Severe retraction of the tympanic membrane and in the expert view of the consultant that this may be reversible and reversing it may help avoid erosion of the ossicular chain or the development of cholesteatoma **or**
 - c) Eustachian tube dysfunction that prevents the commencement or completion of hyperbaric oxygen treatment.**or**
 - d) acute or chronic otitis media with risk of complications of facial palsy or intracranial infection e.g. meningitis **or**
 - e) As a treatment for Meniere's disease **or**
 - f) In the case of conditions e.g. nasopharyngeal carcinoma, ethmoidal cancer, maxillectomy, olfactory neuroblastoma, sinusal cancer, and complications relating to its treatment (including radiotherapy), if judged that the risks outweigh the benefit by the responsible clinician **or**
 - g) There is severe pain due to air pressure changes when flying or in hyperbaric treatment. The severity and frequency of flying should be discussed with the patient and balanced against the possible complications associated with grommets
- 2.2 Of note: In cases of otitis media with effusion in adults, grommets are not routinely funded as unlike in children where the outcome of OME is generally good, this is not clear in adults

3. Background to the Condition

3.1 The insertion of grommets, or ventilation tubes, is a common procedure: it may be used to treat otitis media with effusion (OME), which may be idiopathic, atopic or related to nasopharyngeal carcinoma and its treatment. Additionally it is used as a possible treatment for Ménière's disease, for the relief of aural symptoms related to flying, as a part of more extensive ear surgery or as a route of drug delivery to the middle ear.

3.2 A limited literature review failed to find any high quality evidence of the effectiveness of grommets in adults. These recommendations are based almost exclusively on case series.

3.3 Otitis media

- a) Adult OME may be secondary to sinusitis, nasopharyngeal malignancy or be idiopathic in nature.¹ It has been suggested that the use of grommets in adults (as opposed to children) is associated with worse outcomes, with increased likelihood of symptom recurrence. One case series² reported 96% recurrence of symptoms following grommet insertion ($n = 50$, follow-up 27 months); another³ reported 35% recurrence ($n = 53$, follow-up 15-27 months).
- b) According to NICE Clinical Knowledge Summaries (CKS), there is insufficient evidence from relevant clinical trials of evidence reviews on recurrent acute otitis media (AOM) and the effective treatment for adults with grommets (ventilation or tympanostomy tubes). 'Taking an ear swab for culture and sensitivity is considered reasonable', based on what is considered to be good clinical practice from expert opinions⁶.

3.4 Nasopharyngeal cancer

With regards to patients with effusion secondary to nasopharyngeal cancer (and radiotherapy as treatment for this condition), advice seems to be conflicting. One case series⁴ ($n = 30$) concluded that grommet insertion resulted in a significant improvement in hearing, though they also noted increased complications associated with grommets in this patient group. The time course of the improvement is not clear. Another case series⁵ ($n = 163$) commented on significant side effects of otorrhoea and perforation, and concluded that "myringotomy and grommet insertion should not be routinely offered to NPC patients with middle ear effusion". Another group⁶ compared grommet insertion with repeated myringotomy ($n = 100$). They noted a significant increase in middle ear complications and concluded that "grommet insertion is contraindicated in post-irradiation OME". A non-blinded RCT⁷ assessed the role of grommets inserted prior to radiation in patients with NPC. They found no difference in hearing over 4 years of follow-up.

3.5 Retraction pockets

We were unable to identify any evidence relating to grommets as a sole treatment for retraction pockets (as opposed to, for example, excision of the pockets and grommet insertion).

3.6 Evidence for use of grommets for pain on flying:

There is one description of a systematic evaluation of the management of otic barotrauma using modified intravenous cannula. Zhang et al 2013 showed that using a modified 24-gauge IC cannula for tympanotomy tube placement provided middle ear ventilation. 191 tubes were placed for otalgia because of hyperbaric oxygen therapy, 58 tubes were inserted for air travel

prophylaxis and 22 tubes were placed for management of otic barotrauma post-flight. All the patients who had this procedure for prophylaxis experienced regular otic barotrauma symptoms during air travel prior to tube placement. All patients were reviewed at 6 weeks post procedure. This technique worked effectively in 99%, though after 6 weeks 88% of the tubes were found to be extruded. They concluded that given the safety, effectiveness, low risk of complications it provided a simple yet effective therapeutic option for otic barotrauma.

3.7 Ménière's Disease

A case series⁸ of 22 patients with unilateral Ménière's disease which was 'intractable to medical treatment' who were treated with grommets showed improvement in patient symptoms in 68% (patient reported symptoms). A case series⁹ of seven patients treated with grommets for Ménière's disease reported 'substantial' benefit in symptoms in 5 at 24 months and 4 patients at 42 months. In a series¹⁰ of 28 patients suffering Ménière's disease which was refractory to medical treatment, it was found that 82% did not have recurrence over two years of follow-up. It is also noted that ventilation tubes may be a means of drug delivery (gentamicin, dexamethasone) in treatment of Ménière's disease.

4. Rationale to the Decision

4.1 Literature from the NICE, Cochrane database and other scholarly article sources were used to provide rationale for the policy. Furthermore this policy is in line with other CCGs such as West Sussex CCG and Doncaster CCG.

5. References

1. Fickelstein Y. *et al.* *Adult-onset otitis media with effusion.* Archives of Otolaryngology -- Head & Neck Surgery, May 1994, vol./is. 120/5(517-27).
2. Dempster J.H. *et al.* The management of otitis media with effusion in adults. Clinical Otolaryngology & Allied Sciences, June 1988, vol./is. 13/3(197-9)
3. Yung M.W. *et al.* *Adult-onset otitis media with effusion: results following ventilation tube insertion.* Journal of Laryngology & Otolaryngology, November 2001, vol./is. 115/11(874-8).
4. Wei W.I. *et al.* *The efficacy of myringotomy and ventilation tube insertion in middle-ear effusions in patients with nasopharyngeal carcinoma.* Laryngoscope, November 1987, vol./is. 97/11(1295-8)
5. Ho W.K. *et al.* *Otorrhea after grommet insertion for middle ear effusion in patients with nasopharyngeal carcinoma.* American Journal of Otolaryngology, January 1999, vol./is. 20/1(12-5)
6. NICE Clinical Knowledge Summaries *Otitis media - acute*, National Institute of Care and Excellence (NICE), September 2009: Available at: <http://cks.nice.org.uk/otitis-media-acute.scenario:2>, Accessed: 4/09/2016
7. Chen C.Y. *et al.* *Failure of grommet insertion in post-irradiation otitis media with effusion.* Annals of Otolaryngology, Rhinology & Laryngology, August 2001, vol./is. 110/8(746-8)
8. Ho W.K. *et al.* *Randomized evaluation of the audiologic outcome of ventilation tube insertion for middle ear effusion in patients with nasopharyngeal carcinoma.* Journal of Otolaryngology, October 2002, vol./is.31/5(287-93)
9. Park J.J. *et al.* *Meniere's disease and middle ear pressure - vestibular function after transtympanic tube placement* *Acta Laryngologica*, 2009 Dec; 129(12): 1408-13
10. Sugawara K. *et al.* *Insertion of tympanic ventilation tubes as a treating modality for patients with Meniere's disease: a short- and long-term follow-up study in seven cases.* Auris, Nasus, Larynx, February 2003, vol./is.30/1(25-8)
11. Montandon P. *et al.* *Prevention of vertigo in Meniere's syndrome by means of transtympanic ventilation tubes.* Journal of Oto-Rhino-Laryngology & its Related Specialties, 1988, vol./is. 50/6(377-81)
12. Zhang Q, Banks C, Choroomi S, Kertesz T. *A novel technique of otic barotrauma management using modified intravenous cannulae.* European Archives of Otorhinolaryngology. 2013 Sep; 270(10):2627-30. doi: 10.1007/s00405-012-2301-3