

GROMMET INSERTION 18 YEARS AND UNDER PERSISTENCE OF BILATERAL OTITIS MEDIA WITH EFFUSION SECONDARY CARE PRIOR APPROVAL POLICY

Version:	2223.v3b
Recommendation by:	NHS Somerset ICB Clinical Commissioning Policy Forum (CCPF)
Date Ratified:	September 2021
Name of Originator/Author:	EBI Team
Approved by Responsible Committee/Individual:	NHS Somerset ICB Clinical Executive Committee (CEC)
Publication/issue date:	October 2021
Review date:	Earliest of either NICE publication or 3 years from issue
Target audience:	<p>NHS Somerset ICB:</p> <ul style="list-style-type: none"> • NHS Providers • GP Practices • Contracts Team <p>Medical Directors:</p> <ul style="list-style-type: none"> • Taunton & Somerset NHS FT • Yeovil District Hospital NHS FT • Royal United Hospitals Bath NHS FT • Somerset Partnership NHS FT
Application Form	Grommet Insertion 18 years & under with effusion prior approval application form.

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VERSION CONTROL

Document Status:	Current policy
Version:	2223.v3b

DOCUMENT CHANGE HISTORY

Version	Date	Comments
1516.v2	March 2017	Amend remove age 3 years include 18 years and under clarify the criteria
1718.v3	September 2020	Rebranding from IFR to EBI, 3 year review CCPF no amendments
2021.v3a	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address

Equality Impact Assessment (EIA) Form OR EIA Screening Form completed. Date:	April 2018
Quality Impact Assessment QIA. Date:	March 2018
Sponsoring Director:	Sandra Corry
Document Reference:	2223.v3b

1 GENERAL PRINCIPLES (PRIOR APPROVAL)

- 1.1 Funding approval must be secured by primary care/secondary care prior to referring/treating patients for this prior approval treatment
- 1.2 Funding approval must be secured prior to a referral for an assessment/surgery. Referring patients without funding approval secured not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment
- 1.3 On limited occasions, we may approve funding for an assessment only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meets the criteria to access treatment in this policy
- 1.4 Funding approval will only be given where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where it is demonstrated that patients have previously been provided with the treatment with limited or diminishing benefit, funding approval is unlikely to be agreed
- 1.5 Receiving funding approval does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment
- 1.6 The policy does not apply to patients with suspected malignancy who should continue to be referred under 2 week wait pathway rules for assessment and testing as appropriate
- 1.7 Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be encouraged to lose weight further prior to seeking surgery.
<https://www.sciencedirect.com/science/article/pii/S1198743X15007193>
(Thelwall, 2015)
- 1.8 Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing
- 1.9 Where prior approval funding is secured by the EBI service it will be available for a specified period of time, normally one year

2 POLICY CRITERIA - PRIOR APPROVAL

- 2.1 In the following circumstances grommets can be undertaken in secondary care and will not require Prior Approval from the ICB:
 - 2.1.1 18 years and under with disabilities such as Turners or Down's Syndrome

and Cleft Palate where the insertion of the grommets is part of an established pathway of care

- 2.1.2 18 years and under to treat a tympanic membrane retraction pocket

PRIOR APPROVAL CRITERIA

Patients 18 years and under with bilateral Otitis Media with Effusion (OME) and without a secondary disability (such as Down's Syndrome or Cleft Palate) when the following criteria are met:

- 2.2 The persistence of bilateral OME and hearing loss should be confirmed over a period of 3 months before intervention is considered. The child's hearing should be re-tested at the end of this time
- During the active observation period, advice on educational and behavioural strategies to minimise the effects of hearing loss should be offered
 - Auto inflation (e.g. OTOVENT) has been trialled unless contra - indicated

AND

- 2.3 At the end of 3 months the child has persistent bilateral OME with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) prior approval for Grommet insertion should be requested **OR**
- 2.4 At the end of 3 months the child has persistent bilateral OME with a hearing loss less than 25–30 dBHL but there is significant impact of the hearing loss on a child's developmental, social or educational status (one of the below)
- Delay in speech development
 - Poor listening skills
 - Inattention and behavioural problems
 - Educational or behavioural problems attributable to the hearing loss period (the hearing should be retested at the end of this time)

3 BACKGROUND

- 3.1 This policy is based on the NICE Clinical Guideline 60 published 2008¹ - Surgical management of otitis media with effusion in children, with guidance on watchful waiting, requiring a period of 3 months
- 3.2 The **Cochrane Collaboration evidence review** (2010)² provides the following conclusions: 'Evidence suggests that grommets only offer a short-

term hearing improvement in children with simple glue ear (otitis media with effusion or OME) who have no other serious medical problems or disabilities. No effect on speech and language development has been shown

3.3 Glue ear is the build-up of thick fluid behind the ear drum. It is a common childhood disorder, affecting one or both ears, and is the major cause of transient hearing problems in children. The insertion of grommets (ventilation or tympanostomy tubes) into the ear drum is a surgical treatment option commonly used to improve hearing in children with bilateral glue ear as unilateral glue ear results in minimal, if any, hearing disability. This review found that in children with bilateral glue ear that had not resolved after a period of 12 weeks and was associated with a documented hearing loss, the beneficial effect of grommets on hearing was present at six months but diminished thereafter. Most grommets come out over this time and by then the condition will have resolved in most children. The review did not find any evidence that grommets help speech and language development but no study has been performed in children with established speech, language, learning or developmental problems. Active observation would appear to be an appropriate management strategy for the majority of children with bilateral glue ear as middle ear fluid will resolve spontaneously in most children.'

3.4 **Non-surgical interventions**

The following treatments are **not recommended** for the management of OME:

- Antibiotics
- Topical or systemic antihistamines
- Topical or systemic decongestants
- Topical or systemic steroids
- Homeopathy
- Cranial osteopathy
- Acupuncture
- Dietary modification, including probiotics
- Immunostimulants
- Massage
- Autoinflation (OTOVENT) should be considered during the active observation period for children with OME who are likely to cooperate with the procedure

3.5 Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative to surgical intervention where surgery is contraindicated or not acceptable

4 **EVIDENCE BASED INTERVENTIONS PANEL APPLICATION PROCESS**

4.1 Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or Consultant believes

clinical exceptional circumstances exist that warrant deviation from the rule of this policy

- 4.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required
- 4.3 Applications cannot be considered from patients personally
- 4.4 Only electronically completed EBI applications will be accepted to the EBI Service
- 4.5 It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the EBI Panel. This will reassure the Panel that the patient has a reasonable expectation of the outcome of the application and its context
- 4.6 EBI applications are reviewed and considered against clinical exceptionality

For further information on 'clinical exceptionality' please refer to the NHS England information using the link below page 9-13;

- <https://www.england.nhs.uk/wp-content/uploads/2017/11/comm-policy-individual-funding-requests.pdf>

- 4.7 Social, Emotional and Environmental factors *i.e. income, housing, environmental pollution, access to services, family, friends, ethnicity, life experiences etc.* CANNOT be considered with an application
- 4.8 Where appropriate photographic supporting evidence can be forwarded with the application form
- 4.9 An application put forward for consideration must demonstrate some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:
 - Significantly different to the general population of patients with the condition in question
 - Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

5 ACCESS TO POLICY

- 5.1 If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067
- 5.2 **Or write to us:** NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

6 REFERENCES

The following sources have been considered when drafting this policy:

- 6.1 NICE CG60 Surgical Management of Otitis Media with Effusion (2008)
<http://guidance.nice.org.uk/CG60/Guidance/pdf/English>
- 6.2 Browning GG, Rovers MM, 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.