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

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Application Form	Prior Approval Form

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

VERSION CONTROL

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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 CCF no amendments
2021.v3a	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.v3b	November 2023	3 year review, inclusion of NICE ng23 guidance (OME in under 12s). Wording change in 4.6

Equality Impact Assessment EIA	April 2018
Quality Impact Assessment QIA	March 2018
Sponsoring Director:	Bernie Marden
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1 GENERAL PRINCIPLES (PRIOR APPROVAL)

1.1 Funding approval must be secured by primary care/secondary/community 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 meet 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:

a) 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

b) 18 years and under to treat a tympanic membrane retraction pocket

2.2 **PRIOR APPROVAL CRITERIA**

2.2.1 Decision Table
NG233 Otitis media with effusion in under 12s: Decision table 30/08/2023 (nice.org.uk)

2.2.3 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:

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

a) Consider grommets for the management of OME-related hearing loss in children. **[2023]**

b) Discuss the benefits and risks of grommets with the child and their parents and carers and make a shared decision on their use. Cover that there is a risk of perforation of the eardrum, atelectasis, tympanosclerosis and infection associated with grommets. **[2023]**

c) During the active observation period, advice on educational and behavioural strategies to minimise the effects of hearing loss should be offered

d) Consider auto-inflation in children with OME if they are able to engage with the treatment. **[2023]**

e) Do not offer antibiotics to treat OME. **[2023]**

f) Do not offer oral or nasal corticosteroids for OME or OME-related hearing loss. **[2023]**

g) Do not offer antihistamines, leukotriene receptor antagonists, mucolytics, proton pump inhibitors and anti-reflux medications, or decongestants for OME or OME-related hearing loss. **[2023]**

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 3-month audiology reassessment 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)

In bilateral OME (in both ears) with hearing loss, reassess hearing after 3 months. Where the OME with hearing loss is unilateral (in one ear), consider reassessment of hearing after 3 months. Advise on strategies to minimise the impact of hearing loss both at home and in educational settings (see recommendation 1.1.7 in the section on information and advice). **[2023]**

In children who are experiencing hearing difficulties that significantly affect day-to-day living, consider intervening earlier than the 3-month reassessment, see the sections on management of hearing loss, non-surgical management of OME, and surgical management of OME. **[2023]**

- Hearing difficulties (for example, mishearing when not looking at who is speaking, difficulty in a group, asking for things to be repeated)
- Delayed speech and language development
- Ear discomfort tinnitus **[2023]**
- Behavioural problems (particularly lack of concentration or attention), being withdrawn or irritability **or**
- Poor educational progress **or**
- Balance difficulties (for example, clumsiness) **[2023]**
- Have a higher suspicion of OME if the child has any of the following features, but be aware the absence of these features does not rule out OME: a history of:

    - upper respiratory tract infections (URTIs)
    - acute otitis media (AOM)
    - craniofacial anomalies, for example Down syndrome and cleft palate
    - asthma
    - wheezing
    - dyspnoea
    - eczema
    - paroxysmal sneezing/nasal itching
    - urticaria
    - potentially harmful sucking habits (for example finger or dummy sucking and bottle feeding,) and mouth breathing
    - conjunctivitis
    - snoring. **[2023]**

2.5 **Adenoidectomy**

a) Where adenoidectomy & grommet insertion is the recommended treatment, please complete the Adenoidectomy +Grommet prior approval application form

b) When planning grommets for management of OME, consider adjuvant adenoidectomy unless assessment indicates an abnormality with the palate. **[2023]**

c) Discuss the benefits and risks of adenoidectomy with the child and their family or carers and make a shared decision on whether to have the procedure. Include that there is a risk of haemorrhage, and velopharyngeal insufficiency. **[2023]**

2.6 Consider bone conduction devices for children with OME-related hearing loss when:

- their hearing levels are known to fluctuate, or
- there are contraindications to using an air conduction hearing aid (such as a history of otorrhea, or anatomical issues such as narrow ear canals), and this type of device would be better tolerated or is preferred (for example, to avoid the choking risk from the small parts of an air conduction device) [2023]

2.7 Patients who are not eligible for treatment under this policy, please refer to section 3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS on how to apply for funding with evidence of clinical exceptionality

3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

3.1 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

3.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required

3.3 Applications cannot be considered from patients personally

3.4 Only electronically completed EBI applications will be accepted to the EBI Service

3.5 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

3.6 EBI applications are reviewed and considered against clinical exceptionality

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB website and input into the 'Search this website' box clinical exceptionality. Click on the link to access the full NHS description of clinical exceptionality

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

3.7 Where appropriate photographic supporting evidence can be forwarded with the application form

3.8 An application put forward for consideration must demonstrated 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

4 ACCESS TO POLICY

4.1 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

4.2 **Or write to us**: NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

5 REFERENCES

The following sources have been considered when drafting this policy:

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5.1 NICE guideline NG233 Otitis media with effusion in under 12s (2023) https://www.nice.org.uk/guidance/ng233

5.2 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