GROMMET INSERTION
RECURRENT ACUTE OTITIS MEDIA (WITHOUT EFFUSION)
SECONDARY CARE PRIOR APPROVAL POLICY

Version:	2324.v2b
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Application Form	Prior Approval Form

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VERSION CONTROL

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DOCUMENT CHANGE HISTORY		
Version	**Date**	**Comments**
1718.v1	March 2020	New policy template & PALs email address Rebranding from IFR to EBI
1920.v3	September 2020	Update General Principles & EBIP process, 3-year review CCPF no amendments
2021.v2	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.v2a	January 2024	3-year review, no clinical amendments. Amendment to website link on 4.6

Equality Impact Assessment EIA	
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

Emergency admission for rare serious complications of AOM are not restricted by this policy

The Commissioner will agree to fund a surgical referral for a patient with recurrent acute otitis media (without effusion) to include consideration of insertion of grommets, where the following criteria have been met:

2.1 The patient has had at least 5 separate recurrences of acute otitis media (with or without treatment) in the previous 12 months, documented in their primary care records (AOM does not routinely require antibiotics) **OR**

2.2 The patient has an episode of Acute Otitis Media (AOM) associated with any of the following:

a. Intracranial infection

b. Acute mastoiditis

c. Facial paralysis

d. Neck abscess

2.4 Patients who are not eligible for treatment under this policy, please refer to section 4 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS on how to apply for funding with evidence of clinical exceptionality

3 BACKGROUND

3.1 **Guidance on referrals for advice and guidance only**
GPs requests for specialist advice on ear problems where AOM may be a factor, fall outside this policy statement, however funding approval will need to be secured from the Commissioner prior to any subsequent surgery

3.2 **Diagnosis by ENT and/or Audiology**
It is important to obtain a diagnosis for recurrent otorrhoea, in particular to exclude cholesteatoma, which is often referred to secondary care in an advanced stage. Where the GP is unable to obtain a good view of the entire tympanic membrane and confidently state that it is normal in between episodes of otorrhoea, an ENT opinion should be sought. If there is any concern about hearing loss in between these episodes, a referral should be made for audiometry

3.3 **Antibiotics**
The majority of cases of AOM will resolve spontaneously. Without specific treatment symptoms improve within 24 hours in 60% of children and settle within three days in 80% of children. Whilst adequate analgesia should be prescribed in all cases, antibiotics should be avoided in mild-to-moderate cases and when there is diagnostic uncertainty in patients aged 2 years and under. The Somerset ICB infection management guidance should be consulted. http://formulary.somersetcb.nhs.uk/?page_id=203

3.4 A Cochrane Collaboration systematic review has concluded:

3.4.1 Acute otitis media is a common disease of childhood, involving inflammation of the space behind the eardrum (the middle ear cleft). Episodes typically involve a fever and a build-up of pus that stretches the eardrum causing severe pain. The drum may then rupture, relieving the pain, and a discharge of pus enters the ear canal. A small proportion of children suffer with recurrent acute otitis media, which is defined as either three or more acute infections of the middle ear cleft in a six-month period, or at least four episodes in a year

3.4.2 One of the strategies used to treat this condition is the insertion of a miniature plastic ventilation tube (or grommet) into the eardrum, which prevents the painful accumulation of pus in the middle ear. This review aims to assess the evidence for the effectiveness of this treatment in reducing recurrent acute otitis media

3.4.3 We searched for scientific studies which compared treating children with recurrent acute otitis media with either grommets or a non-surgical treatment such as antibiotics (or no treatment). In these studies, children with grommets in place were considered to have suffered an episode of acute otitis media if they had a discharge of pus from the ear

3.4.4 Two suitable studies were found to be suitable for further analysis. The combined results from these two studies suggested that more children treated with grommets are rendered symptom-free in the six months following surgery compared to those who receive other treatments or no treatment. One of the two included studies, involving 95 children, showed that grommets reduce the number of episodes of acute otitis media in the first six months after surgery, by an average of 1.5 episodes per child

3.4.5 When considering the size of this effect, it is important to bear in mind that the studies were not perfect in their design and execution. To be confident in these findings further high-quality research is required.'

4 EVIDENCE BASED INTERVENTIONS 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 funding application are considered against clinical exceptionality. To eliminate discrimination for patients, **social, environmental, workplace, and non-clinical personal factors cannot be taken into consideration.**

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB EBI webpage Evidence Based Interventions - NHS Somerset ICB and click on the section titled Generic EBI Pathway

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

4.8 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

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 McDonald S, Langton Hewer CD, Nunez DA. Grommets (ventilation tubes) for recurrent acute otitis media in children. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD004741. DOI: 10.1002/14651858.CD004741.pub2