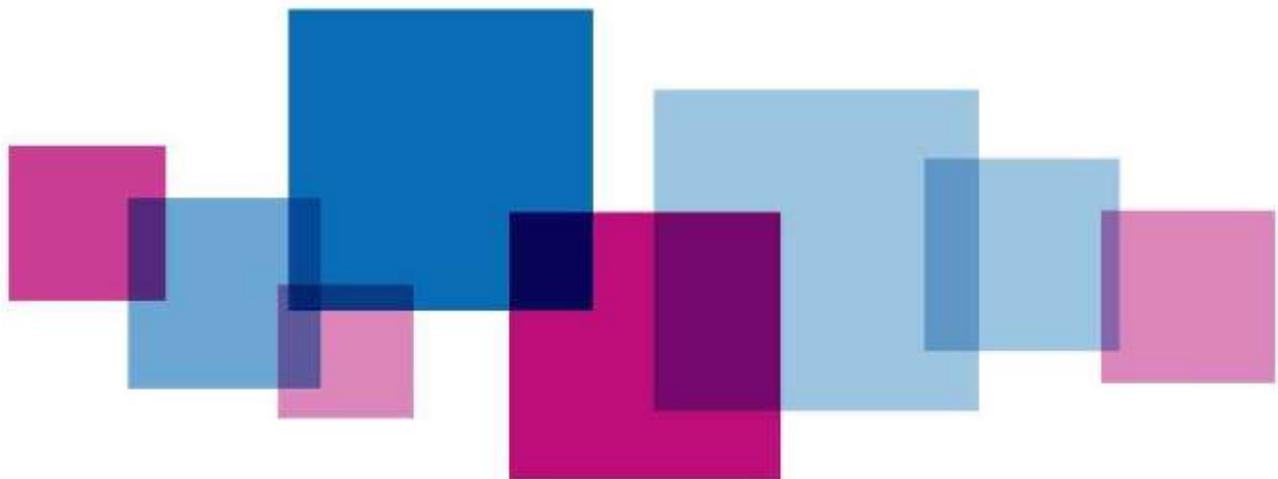


# **Commissioning Policy**

## **Surgical Referral for Children under 12yrs with Persistent Otitis Media with Effusion (Insertion of Grommets)**

**Criteria Based Access and Individual  
Funding Request Policy**



**Date Adopted: 1<sup>st</sup> September 2019**  
**Version: 1920.1.03**

## Document Control

<b>Title of document:</b>	Surgical Referral for Children under 12yrs with Persistent Otitis Media with Effusion (Insertion of Grommets)
<b>Authors job title(s):</b>	Commissioning Policy Development Manager
<b>Document version:</b>	v1920.1.03
<b>Supersedes:</b>	v1617.1.01
<b>Clinical Engagement received from :</b>	ENT Consultant –UHB ENT Consultant - UHB
<b>Discussion and Approval by Commissioning Policy Review Group (CPRG):</b>	18/ 06 /2019
<b>Discussion and Approval by ICB Commissioning Executive:</b>	11/07/2019
<b>Date of Adoption:</b>	01/09/2019
<b>Publication/issue date:</b>	July 2019
<b>Review due date:</b>	Earliest of either NICE publication or three years from approval.
<b>Equality Impact Assessment Screening (date completed):</b>	May 2019
<b>Quality Impact Assessment Screening (date completed):</b>	May 2019
<b>Patient and Public Involvement</b>	May 2019

## Version Control

Version	Date	Reviewer	Comment
v1617.1.01	26/03/2018	IFR Coordinator	Rebranded to BNSSG ICB



v1920.1.00	29.04.2019	Commissioning Policy	Statement added in to reflect NHS England Evidence Based Interventions request for due
		Development Support Manager	regard. Clinical review and amendment to criteria following this review. Rebranded template.
V1920.1.01	23.05.2019	Commissioning Policy Support Officer	Admin change
1920.1.02	03/06/2019	Commissioning Policy Development Manager	Admin Corrections for CPRG and inclusion of OPCS codes
1920.1.03	20/06/2019	Commissioning Policy Development Manager	Post CPRG admin amendments to include restrictions to complex conditions criteria and inclusion of Remedy link

**THIS IS A CRITERIA BASED ACCESS POLICY**

**TREATMENT MAY BE PROVIDED WHERE PATIENTS MEET THE CRITERIA BELOW**

**THIS POLICY RELATES TO ALL PATIENTS under 12 YEARS**

## **Surgical Referral for Children under 12yrs with Persistent Otitis Media with Effusion (Insertion of Grommets) Policy**

### **General Principles**

Treatment should only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB Exceptional Funding Request Panel.



1. Clinicians should assess the patients against the criteria within this policy prior to referring patients seeking treatment. Referring patients to secondary care that do not meet these criteria 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.
2. Patients should be given advice on self-management and care in order to be managed conservatively.
3. Patients will only meet the criteria within this policy where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment and the EFR team should be approached for advice.
4. On limited occasions, the ICB may approve funding for a further assessment in secondary care 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.
5. Where funding approval is given by the Exceptional Funding Request Panel, it will be available for a specified period of time, normally one year.
6. 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).
7. Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing (ASH, 2016)
8. In applying this policy, all clinicians and those involved in making decisions affecting patient care will pay due regard to the need to eliminate unlawful discrimination, harassment, victimisation, etc., and will advance equality of opportunity and foster good relations between people who share a protected characteristic and those who do not. In particular, due regard will be paid in relation to the following characteristics protected by the Equality Act 2010: age, disability, sex, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief and sexual orientation.

## Background / Purpose and Scope

Otitis media with effusion (OME) is a common condition of early childhood in which an accumulation of fluid within the middle ear space causes hearing impairment. The hearing loss is usually transient and self-limiting over several weeks, but may be more persistent and lead to educational, language and behavioural problems. It is most common in young children, with a bimodal peak at 2 and 5 years of age; 80% of children will have had at least one episode of

OME by the age of 10 years.

In most instances of uncomplicated OME, no intervention is required because the fluid clears spontaneously. Parents of children should be advised that parental smoking increases the risk of OME.

## **NHS England Definition of Intervention**

Evidence suggests that grommets only offer a short-term hearing improvement in children with glue ear who have no other serious medical problems or disabilities. They should be offered in cases that have a history of persistent (at least 3 months) bilateral, hearing loss as defined by the NICE guidance. Hearing aids can also be offered as an alternative to surgery<sup>22</sup>.

### **Management of hearing impairment**

During the active observation period, advice on educational and behavioural strategies to minimise the effects of the hearing loss should be offered. Parents of children with hearing loss should be advised on strategies to promote learning for their child in the home and school:

- When speaking to the child, face them, slow the rate of speech, raise the level, and speak clearly.
- Turn off competing auditory stimuli, such as music or television.
- Daily reading helps language development. Books with explanatory pictures are useful.
- Discuss seating arrangements with the school, ideally placing the child near the teacher.

Parents with concern of speech, language and developmental delay of their child should be advised that the evidence shows that the child quickly recovers following resolution of the OME. (NICE, 2011).

### Nasal Balloon - Otovent

Otovent autoinflation device (nasal balloon) allows for a safe, natural treatment to relieve the symptoms of glue ear without drugs or surgery. It works by using pressure to open the Eustachian tube allowing the fluid to drain from the inner ear (Otovent, 2016).

NICE have included the recommendation “Autoinflation may be considered during the active observation period for children with OME who are likely to cooperate with the procedure.” In addition, they have published MIB59 “Otovent nasal balloon for otitis media with effusion” showing that four randomised controlled trials, all in children, have shown that using the device causes significant improvements, compared with standard care, in middle ear function; one of the trials also reported a significant reduction in the need for ventilation tube (grommet) insertion surgery (NICE, 2016).

This device is now able to be prescribed on the NHS or is readily available on the high



street/internet without prescription and is something that patient's may find beneficial to try before proceeding on a surgical pathway.

## **Risk**

As with any operation, there is a risk of complications from the surgery and with the anaesthetic. However, the risk is very small. Other potential complications of the surgery include:

- Infection - Grommets may cause more frequent ear infections. About 10% of patients will get intermittent symptoms (normally associated with having a cold), 1% will have significant enough symptoms to require the removal of the grommet.
- Perforation - most grommets will fall out on their own after nine to eighteen months. When they do, the ear drum heals up after them, but they may leave a small hole in the ear drum which may need to be fixed. 2 - 3% of patients will develop this complication.
- Minor damage and scarring to the eardrum, particularly in revision surgery, may occur but this is unlikely to cause any problems. (NHS Choices, 2016)

**POLICY CRITERIA – COMMISSIONED**

**CRITERIA BASED ACCESS**

The ICB will agree to fund a surgical intervention for children with otitis media with effusion (OME) under 12 years, to include consideration of insertion of grommets, where the following criteria have been met:

**Policy - Criteria to Access Treatment – CRITERIA BASED ACCESS**

Primary care should make a referral to Audiology so that they may assess the patient's hearing levels against this section of the policy and they will list for treatment should the patient meet this criteria.

**Persistent bilateral OME with significant hearing loss**

1. Treatment of children in this section of the policy must meet the following criteria:

- a) The child has persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of at least 25 dBHL (decibel hearing level) or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available).

**OR**

- b) The child has documented developmental or educational problems with persistent OME and hearing loss less severe than 25–30 dBHL in the better ear

**AND**

- 2. The persistence of bilateral OME and hearing loss has been confirmed at a 3 month audiological assessment.

**AND**

- 3. No later than the 3 month audiological assessment

For audit purposes secondary care patient care records should show that:

- Parents/carers and children have been given information on the nature and effects of OME, including its usual natural resolution.
- Parents/carers and children have been given the opportunity to discuss options for

- treatment of OME, including their benefits and risks.
- Verbal information about OME has been supplemented by written information appropriate to the stage of the child's management

*Surgery will not be funded if less than 3 months (12 weeks) has elapsed between the first and 2nd confirmatory audiological tests required above showing a persistent need*

**Policy - Criteria to Access Treatment – CRITERIA BASED ACCESS**

**Early intervention for bilateral OME in children with additional health needs**

Insertion of grommets before 3 months of watchful waiting has elapsed is commissioned for children meeting the following criteria:

- a) urgent surgery required for airway impairment secondary to adeno-tonsillar hypertrophy
- OR**
- b) coexistent severe or profound hearing loss (defined as at least 61 dBHL).

**Policy - Criteria to Access Treatment – CRITERIA BASED ACCESS**

Assess the patient against this section of the policy and list for treatment should they meet this criteria:

**Insertion of grommets to support diagnosis and treatment of complex conditions**

Insertion of grommets is commissioned for diagnostic or other preparatory purposes where OME is considered clinically relevant in:

- a) Children preparing for insertion of cochlear implants
- OR**
- b) Children with severe learning difficulties.

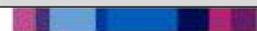
The period of watchful waiting in these cases should be based on the overall health needs and treatment schedule for the child.

**Restrictions:**

It is expected that fewer than 10 patients a year will undergo the procedure under the above access criteria; if this is exceeded, mechanisms of review of the commissioning and contracting will be initiated between lead commissioners

**In addition to the above access criteria, funding is also available where it is evidenced:**

- Healthcare professionals consider surgical intervention is appropriate in a child who cannot undergo standard assessment of hearing thresholds where there is clinical and



Tympanographic evidence of persistent glue ear and where the impact of hearing loss on a child's developmental, social or educational status is judged to be significant.

- The patient has Downs Syndrome and/or Cleft Palate these patients may be offered.

grommets after a specialist MDT assessment in line with NICE guidance .

- It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed. Whilst waiting for surgery a repeat tympanometry, as a minimum should be considered if previous tests are greater than 3 months old.

### **Revision Surgery – reinsertion of grommets for children under the age of 12 years.**

Children who have a recurrence of OME, with significant hearing loss, following a previous surgery can access this intervention again where the treating clinician believes further surgery would be of benefit. The patient would once again be subjected to this restricted policy.

## **Due Regard**

In carrying out their functions, the Bristol North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which the ICBs are responsible, including policy development and review.

Consideration has been given to this policy and the development process of the above criterion following the recent NHSE Evidence-Based Interventions (EBI) recommendations and local clinicians have confirmed that this criteria supports the recommendations made in regard to the current clinical evidence available.

Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the ICB's Exceptional Funding Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800**



073 0907 or email them on [BNSSG.customerservice@nhs.net](mailto:BNSSG.customerservice@nhs.net) .

## Connected Policies

- **Surgical Referral for Children under 18yrs with recurrent Otitis Media with Effusion (Insertion of Grommets):** Clinician's should refer to the intervention specific policy.

- **Myringotomy and Insertion of Grommets patients aged 12yrs Or Over) with Otitis Media With Effusion:** Clinician's should refer to the intervention specific policy.

## This policy has been developed with the aid of the following references:

- Ash. (2016). *Ash.org.uk*. Retrieved Sept 24, 2018, from [www.ash.org.uk](http://www.ash.org.uk): [www.ash.org.uk/briefings](http://www.ash.org.uk/briefings)
- Browning, G., Rovers, M., Williamson, I., Louis, J., & Burton, M. (n.d.).  
<https://ora.ox.ac.uk/objects/uuid:fb64725b-5d82-41ad-9284-26d7cb0370b7>. Retrieved 4 29, 2019, from <https://ora.ox.ac.uk/>: <https://ora.ox.ac.uk/objects/uuid:fb64725b-5d82-41ad-9284-26d7cb0370b7>
- Loof S., D. B. (2014). Perioperative complications in smokers and the impact of smoking cessation interventions [Dutch]. *Tijdschrift voor Geneeskunde*, vol./is. 70/4(187-192).
- Lous J, B. M. (2005, January). *NCBI - Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children*. Retrieved May 13, 2019, from NCBI:  
<https://www.ncbi.nlm.nih.gov/pubmed/15674886>
- NHS Choices. (2016, February 28). *Middle ear infection (otitis media)* . Retrieved from NHS Choices:  
<http://www.nhs.uk/Conditions/Otitis-media/Pages/Introduction.aspx>
- NHS England Medical directorate and Strategy and Innovation directorate. (n.d.).  
<https://www.englahttps://www.england.nhs.uk/publication/evidence-based-interventions-response-to-the-public-consultation-and-next-steps/>. Retrieved 4 24, 2019, from <https://www.england.nhs.uk>: <https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-consultation-response-document-v2.pdf>
- NICE - *Otitis media with effusion in under 12s: surgery*. (2008, February). Retrieved May 13, 2019, from NICE: <https://www.nice.org.uk/Guidance/CG60>
- NICE. (2011, March). Retrieved from National Institute for Health and Care Excellence:  
<http://cks.nice.org.uk/otitis-media-with-effusion#!supportingevidence>
- NICE. (2016, March). *Otovent nasal balloon for otitis media with effusion*. Retrieved from NICE:  
<https://www.nice.org.uk/advice/mib59>
- Otovent. (2016). *Glue Ear? Don't just watch and wait. Act now*. Retrieved from Otovent:  
[http://www.gluear.co.uk/?gclid=CNy6z6XH\\_80CFfMW0wodWhEO4g](http://www.gluear.co.uk/?gclid=CNy6z6XH_80CFfMW0wodWhEO4g)
- Thelwall, S. (2015). Impact of obesity on the risk of wound infection following surgery: results from a nationwide prospective multicentre cohort study in England. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases*, vol. 21, no. 11, p. 1008.e1.

## **OPCS Procedure codes**

Procedures challenged in this policy:

OPCS Code: D151, D158, D159, D202, D201

Relevant diagnoses for this policy:

ICD10 Code: None

Diagnoses for which the above procedures are permitted:

ICD10 Codes: H65, H650, H651, H652, H653, H654 and H659