NHS
Dorset
Clinical Commissioning Group

NHS Dorset Clinical Commissioning Group / NHS England (Children)

GROMMET/VENTILATION TUBE

Criteria Based Access Protocol



Supporting people in Dorset to lead healthier lives

NHS DORSET CLINICAL COMMISSIONING GROUP

GROMMET/VENTILATION TUBE CRITERIA BASED ACCESS PROTOCOL

1. INTRODUCTION AND SCOPE

1.1 This protocol describes the exclusions and access criteria regarding ventilation tube surgery and will be applied in accordance with the Policy for Individual Patient Treatment.

1.2 NHS Dorset Clinical Commissioning Group will only support ventilation tube insertion in the case of clinical need, where the patient meets the criteria indicated below.

1.3 This Protocol is a consequence of the following NICE and professional guidance:

- NICE Clinical Guideline 60 – Surgical management of otitis media with effusion in children;
- SIGN Guideline No. 66 - Diagnosis and Management of Childhood Otitis Media in Primary Care;
- The Cochrane Collaboration – Grommets (ventilation tubes) for recurrent acute otitis media in children (Review) 2008.

1.4 This policy has been furthered reviewed to meet the NHS England Evidence Based Intervention Criteria in relation to Grommets for children, January 2019. 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

2. DEFINITIONS

2.1 Any definitions related to this Criteria Based Access Protocol are included as a Glossary at Appendix B.

3. ACCESS CRITERIA

3.1 In the circumstances below, the reason for referral against these criteria will be clearly documented in the notes, and in the referral to secondary care. This will enable random audits to confirm compliance with these guidelines.

Children (Up to 16 Years)

3.2 Where children meet one of the following criteria, general practitioners may refer the patient for consideration for insertion of ventilation tubes, and will not need to have individual approval from commissioners:

- Disabilities such as Turners or Downs Syndrome and Cleft Palate where the insertion of the ventilation tubes is part of an established pathway of care;
- Clinically significant tympanic membrane retraction pocket in pars tensa;

- Bilateral Otitis Media with Effusion (OME) when ALL of the following criteria are met:

  a) The child is between three and 16 years of age and must have had specialist audiology and ENT assessment; and
  b) there has been a period of watchful waiting for at least 3 months with a definitive diagnosis of OME, and OME persists; and
  c) the child has poor listening skills, indistinct speech or delayed language development; inattention and behaviour problems; and
  d) the child has a documented hearing level in the better ear of 25 dBHL or worse averaged at 0.5,1,2 and 4 kHz (or equivalent dBA where dBHL not appropriate for age).

- Frequent episodes (at least six episodes within 12 months) of acute otitis media (AOM), or complications, which are documented in primary care records.

3.2.1 The persistence of bilateral OME and hearing loss should be confirmed over a period of three 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.

Adults

3.3 Where adults meet one of the following criteria, general practitioners may refer the patient for consideration for insertion of ventilation tubes and will not need to have individual approval from commissioners:

- Otitis Media with Effusion (OME) when ALL of the following criteria are met:
  a) there has been a period of watchful waiting for at least 3 months with a definitive diagnosis of OME, and OME persists; and
  b) the patient has a documented hearing level in the better ear of 30 dBHL or worse averaged at 0.5,1,2 and 4 kHz.
  c) where conventional hearing aids are not clinically appropriate

  The persistence of OME and hearing loss should be confirmed over a period of 3 months before intervention is considered. The patient's hearing should be re-tested at the end of this time.

- Clinically significant tympanic membrane retraction pocket in pars tensa;
- As part of middle ear major surgery;
- Hearing loss post-radiotherapy where hearing aids are not clinically appropriate;
- As part of post-nasal space biopsy for cancer investigation.

Re-insertion of Ventilation Tubes

3.4 For both children and adults – where a ventilation tube has been inserted and fallen out, insertion of a second or subsequent ventilation tube may be considered where the patient meets the one of the above criteria (including the requirements for 'watchful waiting').

Adults

- If a second or subsequent ventilation tube is required, the secondary care clinician must seek individual approval from the commissioner and consideration must be given to the appropriateness of using a T-tube;

Children

- Where the criteria above are met, up to three sets of temporary ventilation tubes may be inserted. If a fourth or subsequent ventilation tube is required, the secondary care clinician must seek individual approval from the commissioner and consideration must be given to the appropriateness of using a T-tube.

4. EXCLUSIONS

4.1 Adenoidectomy, including where undertaken as an adjuvant intervention is not supported in the absence of persistent and/or frequent upper respiratory tract symptoms.

5. CASES FOR INDIVIDUAL CONSIDERATION

5.1 Should a patient not meet the criteria detailed within this protocol, the Policy for Individual Patient Treatments (which is available on the NHS Dorset Clinical Commissioning Group website or upon request), recognises that there will be occasions when patients who are not considered for funding may have good clinical reasons for being treated as exceptions. In such cases the requesting clinician must provide further information to support the case for being considered as an exception.

5.2 The fact that treatment is likely to be effective for a patient is not, in itself a basis for exceptional circumstances. In order for funding to be agreed there must be some unusual or unique clinical factor in respect of the patient that suggests that they are:

- significantly different to the general population of patients with the particular condition; and
- they are likely to gain significantly more benefits from the intervention than might be expected for the average patient with the condition

5.3 In these circumstances, please refer to the Individual Patient Treatment Team at the address below:

First Floor West
Vespasian House
Barrack Road
Dorchester
DT1 1TG
Telephone no: 01305 368936
Email: individual.requests@dorsetccg.nhs.uk

6. INFORMATION FOR PATIENTS

6.1 The provision of information understandable to patients is central to the consent process. All patients should be provided with information on Grommets / Ventilation Tubes.

6.2 In all cases, GPs should provide patients with information related to Grommets on NHS Choices (http://www.nhs.uk/Conditions/Otitis-media/Pages/Treatment.aspx)

6.3 The Royal college of Surgeons recommends that patient are aware of the following sources of information:

- **Glue ear decision aid (2012),** Right Care http://sdm.rightcare.nhs.uk/pda/glue-ear/
- **Glue ear: a guide for families,** National Deaf Children's Society (NDCS) http://www.ndcs.org.uk/family_support/glue_ear/
- **Harvey gets grommets,** NDCS http://www.ndcs.org.uk/family_support/glue_ear/
- **Glue ear (OME),** ENT UK https://entuk.org/docs/patient_info_leaflets/09023_glue_ear

7. CONSULTATION

7.1 Prior to previous version approval from Dorset CCG's Clinical Commissioning Committee this Protocol was reviewed by the Maternity and Family Health CDG which includes commissioners, clinicians and other relevant stakeholders. National consultation in relation to the NHSE updated guidance for grommets in children was undertaken between July 2018 and November 2018.

7.2 An Equality Impact Assessment for this Criteria Based Access Protocol is available on request.

8. RECOMMENDATION AND APPROVAL PROCESS

8.1 This access protocol has been approved on behalf of the Clinical Reference Group in line with processes agreed by the CCG's Governing Body.

9. COMMUNICATION/DISSEMINATION

9.1 Following approval of Criteria Based Access Protocols at Clinical Reference Group each Protocol will be uploaded to the CCG's Intranet, Internet and added to the next GP Bulletin.

10. IMPLEMENTATION

10.1 Following review of this Criteria Based Access Protocol it was agreed there were no new aspects to be included in this version and therefore no requirement for an implementation plan.

11. DOCUMENT REVIEW FREQUENCY AND VERSION CONTROL

11.1 This Criteria Based Access Protocol requires a review every three years, or in the event of any changes to national guidance or when new guidance is issued.

APPENDIX A

FREQUENTLY ASKED QUESTIONS

N/A

GLOSSARY

N/A

APPENDIX C

A	DOCUMENT DETAILS
Procedural Document Number	99
Author (Name and Job Title)	Tracey hall, Head of Elective Care
Clinical Delivery Group (recommending group)	Clinical Reference Group
Date of recommendation by CRG	April 2017
Date of approval	April 2019 (NHSE update – children)
Version	3.2
Review frequency	3 yearly
Review date	April 2020 (adults) February 2022 (children)

B	CONSULTATION PROCESS		
Version No	**Review Date**	**Author and Job Title**	**Level of Consultation**
3.0	May 2016	Kate Halsey, Senior Programme Lead	Dr Julie Doherty, Paediatric Consultant and Clinical Director for Children's Services, DCHFT
3.2	March 2019	Tracey Hall, Head of Elective Care	NHSE Consultation July 2018 to November 2018

C	VERSION CONTROL				
Date of recommendation	**Version No**	**Review date**	**Nature of change**	**Approval date**	**Approval Committee**
June 16	3.0	June 19	Review of protocol and change to new format	June 16	CCC
February 17	3.1	Feb 20	Clarification that adenoidectomy not supported whether as an adjuvant intervention or in isolation	April 17	CCC
January 2019	3.2	January 22	Checked against NHSE issued criteria and referenced to this.	April 2019	NHSE

D	ASSOCIATED DOCUMENTS
• Policy for individual patient treatment, NHS Dorset Clinical Commissioning Group • Making sense of Local Access Based Protocols, NHS Dorset Clinical Commissioning Group • NHS England Evidence Based Interventions – Guidance for CCGs, January 2019	

E	SUPPORTING DOCUMENTS/EVIDENCE BASED REFERENCES	
Evidence	**Hyperlink (if available)**	**Date**
NICE Clinical Guideline 60 – Surgical management of otitis media with effusion in children.	http://guidance.nice.org.uk/CG60/Guidance/pdf/English	2008
SIGN Guideline No. 66 - Diagnosis and Management of Childhood Otitis Media in Primary Care.	http://www.sign.ac.uk/guidelines/fulltext/66/index.html	2003
The Cochrane Collaboration – Grommets (ventilation tubes) for recurrent acute otitis media in children (Review).	http://www2.cochrane.org/reviews/en/ab004741.html	2008

Royal College of Surgeons: Commissioning guide: Otitis media with effusion. Other evidence and information can be found at p26 NHSE Evidence Based Interventions – Guidance for CCGs	https://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/ome https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf	2013 2019

F	DISTRIBUTION LIST		
Internal CCG Intranet	**CCG Internet Website**	**Communications Bulletin**	**External stakeholders**
✓	✓	✓	✓