

CLINICAL POLICY ADVISORY GROUP (CPAG)

Grommets in Otitis Media with Effusion Policy

This procedure requires prior approval. Prior approval must be sought through Blueteq.

Criteria:

■ **Black – criteria required to be met prior to referral**

■ **Blue – criteria to be met prior to procedure**

Statement

NHS Derby and Derbyshire ICB (NHS DDICB), in line with its principles for procedures of limited clinical value, has deemed grommets should not be routinely commissioned for children and adults unless the criteria in this policy are met:

Children

Children over the age of two, who have bilateral otitis media with effusion (OME), which is having an impact on the child's hearing that persists after a period of at least three months of watchful waiting from the date that the problem was first identified by the GP to the date of referral. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter' in those children thought to tolerate the procedure (usually at least 3 years old). If these do not improve symptoms, children can be referred if they meet one of the following criteria:

There have been at least 5 recurrences of acute otitis media, which required medical assessment and/or treatment in the last 12 months. In cases of recurrent OME, adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.

There is hearing loss of at least 25-30dB in the better ear (pure tone audiometry findings averaged across all four tones).

There is evidence of delay in speech development, educational or behavioural problems attributable to the hearing loss

A significant second disability that may itself lead to developmental problems (such as Down's syndrome, Turner's syndrome of a cleft palate).

Adults

Adults with OME if at least one of the following criteria are met:

A period of 3 months of watchful waiting prior to referral. Significant negative middle ear pressure measured on two sequential appointments, with no resolution within 3 months of first presentation. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter'. If these do not improve symptoms, hearing aids should be the next intervention offered prior to further treatment.

Repetitive acute otitis media (AOM) (3 episodes in 6 months or 4 in 12 months) when it does not respond to ongoing antibiotic therapy and impairs speech, hearing or both.

Barotrauma (persistent Eustachian tube dysfunction): Damage from changes in pressure, such as scuba diving or flying, causing pain.

Unilateral middle ear effusion where a post-nasal space examination and/or biopsy is required to exclude underlying malignancy.

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

1. Background

Otitis media with effusion (OME) is a condition characterized by a collection of fluid within the middle ear space without signs of acute inflammation. OME can be associated with significant hearing loss, especially if it is bilateral and lasts for longer than one month. Often, when the hearing loss is affecting both ears it can cause language, educational and behavioural problems.

The exact cause of OME is uncertain, but over 50% of cases are thought to follow an episode of acute otitis media (AOM), especially in children under 3 years of age. Persistent OME can occur because of the following:

- Impaired eustachian tube function causing poor aeration of the middle ear.
- Low-grade viral or bacterial infection.
- Persistent local inflammatory reaction.
- Adenoidal infection or hypertrophy

Grommets is a surgical procedure to insert tiny tubes (grommets) into the eardrum as a treatment for fluid build-up (glue ear).

2. Recommendation

This procedure requires prior approval. Prior approval must be sought through Blueteq.

Criteria:

■ **Black – criteria required to be met prior to referral**

■ **Blue – criteria to be met prior to procedure**

Recommendation for Children

The commissioner will fund grommets in children, who are over the age of two, who have bilateral OME which is having an impact on the child's hearing, that persists after a period of at least three months of watchful waiting from the date that the problem was first identified by the GP to the date of referral. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter' in those children thought to tolerate the procedure (usually at least 3 years old). If these do not improve symptoms, children can be referred if they have one of the following:

- There have been at least 5 recurrences of AOM, which required medical assessment and/or treatment in the last 12 months.
 - In cases of recurrent OME, adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.
- There is hearing loss of at least 25-30dB in the better ear. (Pure tone audiometry findings averaged across all four tones)
- There is evidence of delay in speech development, educational or behavioural problems attributable to the hearing loss or a significant second disability that may itself lead to developmental problems, e.g., Down's syndrome, Turner's syndrome or a cleft palate

Recommendation for Adults

The commissioner will fund grommets in adults with OME if at least one of the following criteria is met:

- A period of 3 months of watchful waiting prior to referral. Significant negative middle ear pressure measured on two sequential appointments, with no resolution within 3 months of first presentation. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter'. If these do not improve symptoms, hearing aids should be

the next intervention offered prior to further treatment.

- Repetitive AOM (3 episodes in 6 months or 4 in 12 months) when it does not respond to ongoing antibiotic therapy and impairs speech, hearing or both.
- Barotrauma (persistent Eustachian tube dysfunction): Damage from changes in pressure, such as scuba diving or flying, causing pain.
- Unilateral middle ear effusion where a post-nasal space examination and/or biopsy is required to exclude underlying malignancy.

Exclusion Criteria: The Grommets Policy only applies to patients with OME. This policy does not apply to conditions such as Meniere's Disease/existence of retraction pockets and the insertion of grommets in these conditions do not require prior approval.

This procedure requires prior approval. Prior approval must be sought through Blueteq.

3. Rationale for Recommendation

In most cases OME will improve by itself without surgery. During a period of monitoring of the condition a balloon device (e.g., Otovent) can be used by the child if tolerated. This is designed to improve the function of the ventilation tube that connects the ear to the nose. Evidence suggests that grommets only offer short-term hearing improvement in children with no other serious medical problems or disabilities. In situations where OME is not having an impact on the child's hearing, there is no urgent need to consider surgery, regardless of whether the OME is persistent or transient, in light of the risks associated with grommet insertion. Use a shared decision approach to discuss the benefits and risks of grommets with the child and their parents and carers, cover that there is a risk of perforation of the eardrum, atelectasis, tympanosclerosis and infection associated with grommets.

4. Useful Resources

- NHS Website. Glue Ear. <https://www.nhs.uk/conditions/glue-ear/>

5. References

- Evidence Based Interventions. Academy of Medical Royal Colleges. <https://www.aomrc.org.uk/ebi/clinicians/grommets-for-glue-ear-in-children/>
- NICE Clinical Guideline (NG233): Otitis Media with Effusion in Under 12s. Published August 2023. <http://www.nice.org.uk/guidance/ng233> NICE CKS Otitis Media with Effusion, Updated 2021. <https://cks.nice.org.uk/topics/otitis-media-with-effusion/>
- Royal College of Surgeons/ ENT UK (2013) Commissioning Guide: Otitis Media with Effusion <https://www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/otitis-media-guide/>
- Bedfordshire and Hertfordshire CCGs. https://prioritiesforum.org.uk/sites/default/files/policies/2019-03/guidance_72_-_grommets_in_adults_september_2018.pdf

6. Appendices

Appendix 1 - Consultation

All relevant providers/stakeholders will be consulted via a named link consultant/specialist. Views expressed should be representative of the provider/stakeholder organisation. CPAG will consider all views to inform a consensus decision, noting that sometimes individual views and opinions will differ.

Consultee	Date
Consultant ENT Surgeon, CRHFT	April 2022
Consultant ENT Surgeon, UHDBFT	April 2022
Clinical Policy Advisory Group (CPAG)	May 2022
Clinical and Lay Commissioning Committee (CLCC)	June 2022
Clinical Policy Advisory Group (CPAG)	October 2023

Appendix 2 - Document Update

Document Update	Date Updated
<u>Version 5.0</u> <ul style="list-style-type: none">Policy has been updated. This includes the addition of background information, useful resources, references and consultation.	May 2022
<u>Version 5.1</u> <ul style="list-style-type: none">Policy has been updated to reflect NICE Clinical Guideline NG233 and the new DDICB organisation	October 2023

Appendix 3 - PLCV Form (Adult)

Derbyshire PLCV Referral Form
for
"Derbyshire PLCV Prior Approval Service"

Grommets in Otitis Media with Effusion
(Adult)

THIS FORM MUST BE COMPLETED IN FULL AND ATTACHED WITH THE APPROPRIATE CLINICAL INFORMATION TO THE E-REFERRAL SERVICE
"PLCV: - DERBYSHIRE PRIOR APPROVAL PROCESS"

INCOMPLETE FORMS WILL BE RETURNED

A referral for an opinion **should not** go via prior approval as the request is for an opinion not a procedure'. For further information please click on the following links:

<https://www.derbyshireimc.org.uk/position>, [Derby and Derbyshire ICB PLCV position letter](#).

Patient details
Surname
Forename(s)
Address
Post code
Date of birth
NHS Number

Referring GP details
Referring GP
Practice name
Practice address
Post code
Telephone number
GP practice code

Patient Consent	
	Mark or tick boxes below to confirm
I confirm the patient has consented to sharing personal and clinical information contained within this referral form. The Derbyshire Prior Approval Team will process this information, clarify data and communicate with the patient and the GP on the outcome.	<input type="checkbox"/>

By submitting this request you are confirming that you have reviewed this request against relevant policy and believe the patient meets the relevant threshold criteria and therefore you have fully explained to the patient the proposed treatment and they have consented to you raising this referral on their behalf.	<input type="checkbox"/>
Please confirm that you have given PLCV patient leaflet to the patient	<input type="checkbox"/>

Part A - PLCV Criteria	At least ONE must apply
The commissioner will fund grommets in adults with OME if at least one of the following criteria is met:	
A period of 3 months of watchful waiting prior to referral. Significant negative middle ear pressure measured on two sequential appointments, with no resolution within 3 months of first presentation. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter'. If these do not improve symptoms, hearing aids should be the next intervention offered prior to further treatment.	<input type="checkbox"/>
Repetitive acute otitis media (AOM) (3 episodes in 6 months or 4 in 12 months) when it does not respond to ongoing antibiotic therapy and impairs speech, hearing or both.	<input type="checkbox"/>
Barotrauma (persistent Eustachian tube dysfunction): Damage from changes in pressure, such as scuba diving or flying, causing pain.	<input type="checkbox"/>
Unilateral middle ear effusion where a post-nasal space examination and/or biopsy is required to exclude underlying malignancy.	<input type="checkbox"/>
<u>Exclusion Criteria</u>	
Exclusion Criteria: The Grommets Policy only applies to patients with OME. This policy does not apply to conditions such as Meniere's Disease/existence of retraction pockets and the insertion of grommets in these conditions do not require prior approval.	

Additional clinical information that may have a bearing on the application

Additional Patient Information	BOTH must apply
This patient is willing to undergo a surgical procedure should it be offered.	<input type="checkbox"/>
I have discussed with the patient the fact they will be referred for a possible procedure but there is no guarantee that a surgical intervention will be the required outcome following the consultation with the secondary care specialist.	<input type="checkbox"/>

Prior Approval No.	
---------------------------	--

Patient Choice of Provider	
First Choice:	[Manually enter provider name]
Second Choice:	[Manually enter provider name]

<p>I confirm that the patient meets the current clinical guideline/policy for referral for the procedure.</p> <p>Name of referrer: _____ Date: _____</p>	
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Part B - Reason for referral	
Salutations:	Dear colleague,
Preamble/context:	Thank you, Dr. XXX (insert your name here)

Problems - This needs to be auto pulled from the GP system

Relevant SH & FH:

Date to be included	
Smoking status	Single Code Entry: Tobacco consumption
Alcohol	Single Code Entry: Alcohol consumption
Occupation	Single Code Entry: Occupations
Ethnicity	Single Code Entry: Ethnic category - 2001 census
Veteran?	Single Code Entry: Military veteran
Freetext: Detail which might assist timely discharge:	

Medication - Date to be included. The GP's need to have the option to EDIT this once it has been populated.

Allergies - Date to be included. The GP's need to have the option to EDIT this once it has been populated.

Useful values:

BP	Pulse rate	Height	Weight	BMI	HbA1C
Single Code Entry: O/E - blood pressure reading Date	Single Code Entry: O/E - pulse rate	Single Code Entry: O/E - height	Single Code Entry: O/E - weight	Single Code Entry: Body mass index	Date

Please embed any attached items here

Please note any individual patient requirements here (e.g. Wheelchair user)

Appendix 4 - PLCV Form (Children)

Derbyshire PLCV Referral Form
for
"Derbyshire PLCV Prior Approval Service"

**Grommets in Otitis Media with Effusion
(Children)**

**THIS FORM MUST BE COMPLETED IN FULL AND ATTACHED WITH THE
APPROPRIATE CLINICAL INFORMATION TO THE E-REFERRAL SERVICE**
"PLCV: - DERBYSHIRE PRIOR APPROVAL PROCESS"

INCOMPLETE FORMS WILL BE RETURNED

A referral for an opinion **should not** go via prior approval as the request is for an opinion not a procedure'.
For further information please click on the following links:
<https://www.derbyshireimc.org.uk/position>, [Derby and Derbyshire ICB PLCV position letter](#).

Patient details
Surname
Forename(s)
Address
Post code
Date of birth
NHS Number

Referring GP details
Referring GP
Practice name
Practice address
Post code
Telephone number
GP practice code

Patient Consent	
	Mark or tick boxes below to confirm
I confirm the patient has consented to sharing personal and clinical information contained within this referral form. The Derbyshire Prior Approval Team will process this information, clarify data and communicate with the patient and the GP on the outcome.	<input type="checkbox"/>

By submitting this request you are confirming that you have reviewed this request against relevant policy and believe the patient meets the relevant threshold criteria and therefore you have fully explained to the patient the proposed treatment and they have consented to you raising this referral on their behalf.	<input type="checkbox"/>
Please confirm that you have given PLCV patient leaflet to the patient.	<input type="checkbox"/>

Part A - PLCV Criteria	At least ONE must apply
<p>The commissioner will fund grommets in children, who are over the age of two, who have bilateral otitis media with effusion (OME) which is having an impact on the child's hearing, that persists after a period of at least three months of watchful waiting from the date that the problem was first identified by the GP to the date of referral. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter' in those children thought to tolerate the procedure (usually at least 3 years old). If these do not improve symptoms, children can be referred if they meet one of the following criteria:</p>	
<p>There have been at least 5 recurrences of acute otitis media (AOM), which required medical assessment and/or treatment in the last 12 months.</p> <ul style="list-style-type: none"> ○ In cases of recurrent OME, adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms. 	<input type="checkbox"/>
There is hearing loss of at least 25-30dB in the better ear (pure tone audiometry findings averaged across all four tones).	<input type="checkbox"/>
There is evidence of delay in speech development, educational or behavioural problems attributable to the hearing loss or a significant second disability that may itself lead to developmental problems (such as Down's syndrome, Turner's syndrome or a cleft palate).	<input type="checkbox"/>
<p><u>Exclusion Criteria</u></p> <p>Exclusion Criteria: The Grommets Policy only applies to patients with OME. This policy does not apply to conditions such as Meniere's Disease/existence of retraction pockets and the insertion of grommets in these conditions do not require prior approval.</p>	

Additional clinical information that may have a bearing on the application

Additional Patient Information	BOTH must apply
This patient is willing to undergo a surgical procedure should it be offered.	<input type="checkbox"/>
I have discussed with the patient the fact they will be referred for a possible procedure but there is no guarantee that a surgical intervention will be the required outcome following the consultation with the secondary care specialist.	<input type="checkbox"/>

Prior Approval No.	
---------------------------	--

Patient Choice of Provider	
First Choice:	[Manually enter provider name]
Second Choice:	[Manually enter provider name]

I confirm that the patient meets the current clinical guideline/policy for referral for the procedure.	
Name of referrer: _____	Date: _____

Part B - Reason for referral	
Salutations:	Dear colleague,
Preamble/context:	Thank you, Dr. XXX (insert your name here)

Problems - This needs to be auto pulled from the GP system

Relevant SH & FH:

Date to be included	
Smoking status	Single Code Entry: Tobacco consumption
Alcohol	Single Code Entry: Alcohol consumption
Occupation	Single Code Entry: Occupations
Ethnicity	Single Code Entry: Ethnic category - 2001 census
Veteran?	Single Code Entry: Military veteran
Freetext: Detail which might assist timely discharge:	

Medication - Date to be included. The GP's need to have the option to EDIT this once it has been populated.

Allergies - Date to be included. The GP's need to have the option to EDIT this once it has been populated.

Useful values:

BP	Pulse rate	Height	Weight	BMI	HbA1C
Single Code Entry: O/E - blood pressure reading Date	Single Code Entry: O/E - pulse rate	Single Code Entry: O/E - height	Single Code Entry: O/E - weight	Single Code Entry: Body mass index	Date

Please embed any attached items here

Please note any individual patient requirements here (e.g. Wheelchair user)

Appendix 5 - Blueteq Form (Adult)

[Click here to access the guidelines/NICE algorithm](#)

[Click to view NHS Derby and Derbyshire ICB Policies](#)

Prior Approval Form - Prior Approval Form - PLCV - Grommets (Adults) for OME			
PATIENT CONSENT			
I confirm the patient has consented to sharing personal and clinical information contained within this referral form. The Derbyshire Prior Approval Team will process this information, clarify data and communicate with the patient and the GP on the outcome.			<input type="checkbox"/> Yes <input type="checkbox"/> No
By submitting this request you are confirming that you have reviewed this request against relevant policy and believe the patient meets the relevant threshold criteria and therefore you have fully explained to the patient the proposed treatment and they have consented to you raising this referral on their behalf.			<input type="checkbox"/> Yes <input type="checkbox"/> No
Please confirm that you have given PLCV patient leaflet to the patient			<input type="checkbox"/> Yes <input type="checkbox"/> No
APPLICANT DETAILS			
Clinician Making Request:		Trust:	
Clinician Full Name:	<input type="text"/> *	Telephone:	<input type="text"/> *
Contact Email (nhs.net):	<input type="text"/> *		
PATIENT DETAILS			
Patient Name:		GP Practice Name:	
NHS Number:		GP Practice Code:	
Patient DOB:		Is the patient a smoker:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Primary Care Prior Approval Number:	<input type="text"/>		
PROCEDURE CRITERIA			
The commissioner will fund grommets in adults with OME if at least one of the following criteria are met:			
<p>1. Does the patient meet one of the following criteria:</p> <p>A period of 3 months of watchful waiting prior to referral. Significant negative middle ear pressure measured on two sequential appointments, with no resolution within 3 months of first presentation. During this time, auto inflation should be offered as part of self-care and purchased 'over the counter'. If these do not improve symptoms, hearing aids should be the next intervention offered prior to further treatment.</p> <p>OR</p> <p>Repetitive acute otitis media (AOM) (3 episodes in 6 months or 4 in 12 months) when it doesn't respond to ongoing antibiotic therapy and impairs speech, hearing or both.</p> <p>OR</p> <p>Barotrauma (persistent Eustachian tube dysfunction): Damage from changes in pressure, such as scuba diving or flying, causing pain.</p> <p>OR</p> <p>Unilateral middle ear effusion where a post nasal space examination and/or biopsy is required to exclude an underlying malignancy.</p>			<input type="checkbox"/> Yes <input type="checkbox"/> No * Required
ADDITIONAL INFORMATION			
Please provide any additional clinical information that may have a bearing on the application in the text box below.			
SUBMISSION DECLARATION			
I confirm that the above information is complete and accurately describes the patient's condition.			
Submitting User	<input type="text"/> *	Date	<input type="text"/> *

Appendix 6 - Blueteq Form (Children)

[Click here to access the guidelines/NICE algorithm](#)

[Click to view NHS Derby and Derbyshire ICB Policies](#)

Prior Approval Form - Prior Approval Form (PLCV) Grommets (Children) for OME			
PATIENT CONSENT			
I confirm the patient has consented to sharing personal and clinical information contained within this referral form. The Derbyshire Prior Approval Team will process this information, clarify data and communicate with the patient and the GP on the outcome.			<input type="checkbox"/> Yes <input type="checkbox"/> No
By submitting this request you are confirming that you have reviewed this request against relevant policy and believe the patient meets the relevant threshold criteria and therefore you have fully explained to the patient the proposed treatment and they have consented to you raising this referral on their behalf.			<input type="checkbox"/> Yes <input type="checkbox"/> No
Please confirm that you have given PLCV patient leaflet to the patient			<input type="checkbox"/> Yes <input type="checkbox"/> No
APPLICANT DETAILS			
Clinician Making Request:		Trust:	
Clinician Full Name:	<input type="text"/>	Telephone:	<input type="text"/>
Contact Email (nhs.net):	<input type="text"/>		
PATIENT DETAILS			
Patient Name:		GP Practice Name:	
NHS Number:		GP Practice Code:	
Patient DOB:		Is the patient a smoker:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Primary Care Prior Approval Number:	<input type="text"/>		
PROCEDURE CRITERIA			
<p>The commissioner will fund grommets in children, who are over the age of two, who have bilateral otitis media with effusion (OME) which is having an impact on the child's hearing, that persists after a period of at least three months of watchful waiting from the date that the problem was first identified by the GP to the date of referral.</p> <p>During this time, auto inflation should be offered as part of self-care and purchased 'over the counter' in those children thought to tolerate the procedure (usually at least 3 years old). If these do not improve symptoms, children can be referred if they meet one of the following criteria:</p>			
<p>1. Does the patient meet one of the following criteria:</p> <p>There have been at least 5 recurrences of acute otitis media (AOM), which required medical assessment and/or treatment in the last 12 months. In cases of recurrent OME, adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms.</p> <p>OR</p> <p>There is hearing loss of at least 25-30dB in the better ear. (Pure tone audiometry findings averaged across all four tones)</p> <p>OR</p> <p>There is evidence of delay in speech development, educational or behavioural problems attributable to the hearing loss or a significant second disability that may itself lead to developmental problems, e.g., Down's syndrome, Turner's syndrome or a cleft palate</p>			<input type="checkbox"/> Yes <input type="checkbox"/> No
ADDITIONAL INFORMATION			
Please provide any additional clinical information that may have a bearing on the application in the text box below.			
SUBMISSION DECLARATION			
I confirm that the above information is complete and accurately describes the patient's condition.			
Submitting User	<input type="text"/>	Date	<input type="text"/>