NHS
Leeds
Clinical Commissioning Group

Ear, Nose and Throat Commissioning Policies

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Name of responsible committee/individual:	NHS Leeds Clinical Commissioning Group - Quality and Performance Committee /Dr Simon Stockill, Medical Director
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Target audience:	Primary and secondary care clinicians, individual funding request panels, and the public
Document History:	Leeds CCGs Cosmetic Exceptions and Exclusions Policy Feb 2014 Leeds CCGs Targeted Interventions Policy Feb 2014 Leeds CCG Ear, Nose and Throat Commissioning Policies 2016-19

Produced on behalf of NHS Leeds Clinical Commissioning Group

Executive Summary

This policy applies to all Individual Funding Requests (IFR) for people registered with General Practitioners in Leeds

This policy does not apply where NHS Leeds CCG is not the responsible commissioner.

The policy updates all previous policies and must (where appropriate) be read in association with the other relevant Leeds Clinical Commissioning Group commissioning policies, which are to be applied across Leeds , including but not limited to policies on cosmetic exceptions and non-commissioned activity.

All IFR and associated policies will be publically available on the internet for the CCG.

This policy relates specifically to :

Ear, Nose and Throat Commissioning Policies including: Ear reconstruction, earlobe repair, otoplasty, septorhinoplasty, septoplasty, rhinoplasty, tonsillectomy, myringotomy, earwax removal.

Contents

1 Introduction

The Clinical Commissioning Groups (CCGs) (NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG) were established on 1 April 2013 under the Health and Social Care Act 2012 as the statutory bodies responsible for commissioning services for the patients for whom they are responsible in accordance with s3 National Health Service Act 2006. As at 1 April 2018 these three CCGs have merged to become NHS Leeds Clinical Commissioning Group

As part of these duties, there is a need to commission services which are evidence based, cost effective, improve health outcomes, reduce health inequalities and represent value for money for the taxpayer. NHS Leeds CCG is accountable to their constituent populations and Member Practices for funding decisions.

In relation to decisions on Individual Funding Requests (IFR), NHS Leeds CCG has a clear and transparent process and policy for decision making. They have a clear CCG specific appeals process to allow patients and their clinicians to be reassured that due process has been followed in IFR decisions made by the Non Commissioned Activity Panel, Cosmetic Exclusions and Exceptions Panel, or Non NICE Non Tariff Drug Panel (the IFR panels).

Due consideration must be given to IFRs for services or treatments which do not form part of core commissioning arrangements, or need to be assessed as exceptions to Leeds CCG Commissioning Policies. This process must be equitably applied to all IFRs.

All IFR and associated policies will be publically available on the internet for the CCG. Specialist services that are commissioned by NHS England or Public Health England are not included in this policy.

2 Purpose

The purpose of the IFR policy is to enable officers of NHS Leeds CCG to exercise their responsibilities properly and transparently in relation to IFRs, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions in relation to IFRs are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCG.

The policy outlines the process for decision making with regard to services/treatments which are not normally commissioned by the CCG in Leeds, and is designed to ensure consistency in this decision making process.

The policy is underpinned by the following key principles:

- The decisions of the IFR panels outlined in the policy are fair, reasonable and lawful, and are open to external scrutiny.
- Funding decisions are based on clinical evidence and not solely on the budgetary constraints.
- Compliance with standing financial instructions / and statutory instruments in the commissioning of healthcare in relation to contractual arrangements with providers.

Whilst the majority of service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the National Health Service (NHS). This may be due to advances in medicine or the introduction of new treatments and therapies or a new cross-Leeds Clinical Commissioning Group statement. The IFR process therefore provides a mechanism to allow drugs/treatments that are not routinely commissioned by the NHS Leeds CCG to be considered for individuals in exceptional circumstances.

3 Scope

Policy development and review: consultation and engagement

The policy was developed to:

- ensure a clear and transparent approach is in place for exceptional/individual funding request decision making; and
- provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner.

It was originally developed in line with NICE or equivalent guidance where this was available or based on a review of scientific literature. This included engagement with hospital clinicians, general practice, CCG patient advisory groups, and the general public cascaded through a range, mechanisms.

The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy

NHS Leeds CCG has established the processes outlined in this policy to consider and manage IFRs in relation to the following types of requests:

Ear, Nose and Throat Commissioning Policies including: Ear reconstruction, earlobe repair, otoplasty, septorhinoplasty, septoplasty, rhinoplasty, tonsillectomy, myringotomy, earwax removal.

NHS Leeds CCG *does not routinely commission* aesthetic (cosmetic) surgery and other related procedures that are medically unnecessary.

Providing certain criteria are met, the CCG will commission aesthetic (cosmetic) surgery and other procedures to improve the functioning of a body part or where medically necessary even if the surgery or procedure also improves or changes the appearance of a portion of the body.

Please note that, whilst this policy addresses many common procedures, it does not address all procedures that might be considered to be cosmetic. The CCG reserve the right not to commission other procedures considered cosmetic and not medically necessary. This policy is to be used in conjunction with the Individual Funding Requests (IFR) Policy for NHS Leeds CCG and other related policies.

NHS Leeds CCG routinely commission interventional procedures where National Institute for Health and Care Excellence (NICE) guidance arrangements indicate “normal” or

"offered routinely" or "recommended as option(s)" and the evidence of safety and effectiveness is sufficiently robust.

NHS Leeds CCG *do not* routinely commission interventional procedures where NICE guidance arrangement indicates "special", "other", "research only" and "do not use".

The commissioning statements for individual procedures are the same as those issued by NICE. (www.nice.org.uk).

An individual funding request (IFR) may be submitted for a patient who is felt to be an exception to the commissioning statements as per the Individual Funding Request Policy.

The CCG accept there are clinical situations that are unique (five or fewer patients) where an IFR is appropriate and exceptionality may be difficult to demonstrate.

Whilst the CCG is always interested in innovation that makes more effective use of resources, in year introduction of a procedure does not mean the CCG will routinely commission the use of the procedure.

An individual funding request is not an appropriate mechanism to introduce a new treatment for a group or cohort of patients. Where treatment is for a cohort larger than five patients, that is a proposal to develop the service, the introduction of a new procedure should go through the usual business planning process. CCG will not fund interventional procedures for cohorts over 5 patients introduced outside a business planning process.

Endpoints

Following completion of the agreed treatment, a proportionate follow up process will lead to a final review appointment with the clinician where both patient and clinician agree that a satisfactory end point has been reached. This should be at the discretion of the individual clinician and based on agreeing reasonable and acceptable clinical and/ or cosmetic outcomes.

Once the satisfactory end point has been agreed and achieved, the patient will be discharged from the service.

Requests for treatment for unacceptable outcomes post treatment will only be considered through the Individual Funding Request route. Such requests will only be considered where a) the patient was satisfied with the outcome at the time of discharge and b) becomes dissatisfied at a later date. In these circumstances the patient is not automatically entitled to further treatment. Any further treatment will therefore be the Clinical Commissioning Group's discretion, and will be considered on an exceptional basis in accordance with the IFR policy.

NHS Leeds CCG are committed to supporting patients to stop smoking in line with NICE guidance in order to improve short and long term patient outcomes and reduce health inequalities. Referring GPs and secondary care clinicians are reminded to ensure the patient is supported to stop smoking at every step along the elective pathway and especially for flap based procedures (in line with plastic surgery literature: abdominoplasty, panniculectomy, breast reduction, other breast procedures).

4 Definitions

The CCG is not prescriptive in their definitions. Each IFR will be considered on its merits, applying this Policy.

Routinely commissioned – this means that this intervention is routinely commissioned as outlined in the relevant policy, or when a particular threshold is met. Prior approval may or may not be required, refer to the policy for more information.

Exceptionality request – this means that for a service which is not routinely commissioned, or a threshold is not met, the clinician may request funding on the 'grounds of exceptionality' through the individual funding request process. Decisions on exceptionality will be made using the framework defined in the overarching policy 'Individual Funding Requests (IFR) Policy for the Clinical Commissioning Group in Leeds'.

5 Duties

The CCG will delegate its decision making in relation to IFRs to a delegated decision maker/s in accordance with its own scheme of delegation.

A delegated decision maker will attend the relevant IFR panel and will also have responsibility for approving the triage process. The triage process is the process of screening requests to see whether the request meets the policy criteria and which referrals need to be considered by an IFR panel; see sections on IFR panels for more information. This will be detailed in the CCG Scheme of Delegation

6 Main Body of Policy

Exceptionality funding can be applied for in line with the overarching policy through the IFR process if you believe your patient is an exception to the commissioning position. Please refer to the overarching policy for more information.

6.1 Ear Procedures

6.1.1 Ear reconstruction excluding NHS England responsible commissioning

Status- routinely commissioned

Ear reconstruction is considered medically necessary when performed to improve hearing by directing sound in the ear canal, whether the ears are absent or deformed from trauma, surgery, disease, or congenital defect. Prior approval is not normally required.

6.1.2 Earlobe repair

Status- routinely commissioned if traumatic tear else prior approval via IFR process is required.

Repair of a traumatic tear is considered medically necessary within 2 years of injury and prior approval is not required. Earlobe repair to close a stretched pierced hole, in the absence of trauma, is considered cosmetic and prior approval or exceptionality approval is required.

6.1.3 Otoplasty (prominent ear correction)

Status- prior approval via IFR process is always required.
Considered medically necessary in children under the age of 16 where there is evidence of psychological harm or bullying at school AND there is either:

- failure of formation of the ante-helical fold or

- an anteverted concha

Prior approval or exceptionality approval is required.

6.1.4 Grommets for glue ear in children

Status- routinely commissioned if the following criteria are met[1]

The NHS should only commission this surgery for the treatment of glue ear in children when the criteria set out by the NICE guidelines are met:

- All children must have had specialist audiology and ENT assessment.
- Persistent bilateral otitis media with effusion over a period of 3 months.
- Hearing level in the better ear of 25-30dbHL or worse averaged at 0.5, 1, 2, & 4kHz
- Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25-30dbHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.
- Healthcare professionals should also consider surgical intervention in children who cannot undergo standard assessment of hearing thresholds where there is clinical and tympanographic evidence of persistent glue ear and where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant.
- The guidance is different for children with Down's Syndrome and Cleft Palate, these children 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, with tympanometry as a minimum.

The risks to surgery are generally low, but the most common is persistent ear discharge (10-20%) and this can require treatment with antibiotic eardrops and water precautions. In rare cases (1-2%) a persistent hole in the eardrum may remain, and if this causes problems with recurrent infection, surgical repair may be required (however this is not normally done until around 8-10 years of age).

6.1.5 Ear wax removal in secondary care

Status: routinely commissioned if the criteria are met

Follow NICE Clinical Knowledge Summary on Earwax Management https://cks.nice.org.uk/earwax#!scenario (accessed 18.04.18)

Ear wax removal is normally carried out in primary care from age 6 months onwards in the following situations:

- If earwax is totally occluding the ear canal and any of the following are present:
  - Hearing loss
  - Earache

[1] https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf (accessed 05/02/2019)

- Tinnitus
- Vertigo
- Cough suspected to be due to earwax

- If the tympanic membrane is obscured by wax but needs to be viewed to establish a diagnosis.

If the person wears a hearing aid, wax is present and an impression needs to be taken of the ear canal for a mould, or if wax is causing the hearing aid to whistle.

Refer to secondary care only in the following scenarios:

- Refer before irrigation if:
  - The person has (or is suspected to have) a chronic perforation of the tympanic membrane.
  - There is a past history of ear surgery.
  - There is a foreign body, including vegetable matter, in the ear canal.
  - There is a visible tympanic membrane perforation
  - Ear drops have been unsuccessful and irrigation is contraindicated.
- Refer after irrigation if irrigation is unsuccessful (following initial softening with ear drops for at least 14 days)
- Seek immediate advice from an Ear Nose and Throat specialist if severe pain, deafness, or vertigo occur during or after irrigation.
- Refer or seek urgent advice if infection is present and the external canal needs to be cleared of wax, debris, and discharge.

Audiogram referral

- If the person continues to experience hearing loss after wax removal arrange an audiogram.

6.2 Nose related procedures

Status- septoplasty is routinely commissioned; septorhinoplasty or rhinoplasty -prior approval is via IFR process always required.

Leeds CCG considers septo-rhinoplasty medically necessary when any of the following clinical criteria is met:

- Septal deviation causing continuous nasal airway obstruction resulting in nasal **breathing difficulty associated with a bony deviation of the nose, where an operation** on the nasal septum would not be effective in restoring the nasal airway without a simultaneous operation to straighten the nasal bones AND a significant external deformity is present.

- Asymptomatic nasal deformity that prevents access to other intranasal areas when such access is required to perform medical necessary surgical procedures (e.g., ethmoidectomy); or when done in association with cleft palate repair

Leeds CCG considers rhinoplasty to correct the appearance of the external nose a cosmetic surgical procedure. Rhinoplasty may be considered medically necessary only in the following limited circumstances:

- When it is being performed to correct a nasal deformity secondary to congenital cleft lip and/or palate
- Upon individual case review, to correct chronic non-septal nasal airway obstruction from vestibular stenosis (collapsed internal valves) due to trauma, disease, or congenital defect, when all of the following criteria are met:
  - Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing), and
  - Photos demonstrate an external nasal deformity, and
  - There is an average 50 % or greater obstruction of nares (e.g., 50 % obstruction of both nares, or 75 % obstruction of one nare and 25 % obstruction of other nare, or 100 % obstruction of one nare), documented by internal inspection of the nose by an ENT surgeon, endoscopy, CT scan or other appropriate imaging modality, and
  - Obstructive symptoms persist despite conservative management for three months or greater, which includes, where appropriate, nasal steroids; and
  - Airway obstruction will not respond to septoplasty and turbinectomy alone

Documentation of these criteria should include:

- ALL requests for septorhinoplasty or rhinoplasty MUST include medical photography- showing the standard 4-way view – base of nose, anterior posterior (AP), and right and left lateral views; AND
- Relevant history of accidental or surgical trauma, congenital defect, or disease (e.g., Wegener's granulomatosis, choanal atresia, nasal malignancy, abscess, septal infection with saddle deformity, or congenital deformity); AND
- Documentation of duration and degree of symptoms related to nasal obstruction, such as chronic rhinosinusitis, mouth breathing, etc.; AND
- Documentation of results of conservative management of symptoms

Leeds CCG considers rhinoplasty cosmetic for all other indications.

6.3 Tonsillectomy for Recurrent Tonsillitis

Status- routinely commissioned if the following criteria met[2]

The NHS should only commission this surgery for treatment of recurrent severe episodes of sore throat when the following criteria are met, as set out by the SIGN guidance and supported by ENT UK commissioning guidance:

- Sore throats are due to acute tonsillitis AND
- The episodes are disabling and prevent normal functioning AND
- Seven or more, documented, clinically significant, adequately treated sore throats in the preceding year OR
- Five or more such episodes in each of the preceding two years OR
- Three or more such episodes in each of the preceding three years.

There are a number of medical conditions where episodes of tonsillitis can be damaging to health or tonsillectomy is required as part of the on-going management. In these instances tonsillectomy may be considered beneficial at a lower threshold than this guidance after specialist assessment:

[2] https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf (accessed 05/02/2019)

- Acute and chronic renal disease resulting from acute bacterial tonsillitis.
- As part of the treatment of severe guttate psoriasis.
- Metabolic disorders where periods of reduced oral intake could be dangerous to health.
- PFAPA (Periodic fever, Apthous stomatitis, Pharyngitis, Cervical adenitis)
- Severe immune deficiency that would make episodes of recurrent tonsillitis dangerous

Further information on the Scottish Intercollegiate Guidelines Network guidance can be found here: http://www.sign.ac.uk/assets/sign117.pdf

Please note this guidance only relates to patients with recurrent tonsillitis. This guidance should not be applied to other conditions where tonsillectomy should continue to be funded, these include:

- Obstructive Sleep Apnoea / Sleep disordered breathing in Children
- Suspected Cancer (e.g. asymmetry of tonsils)
- Recurrent Quinsy (abscess next to tonsil)
- Emergency Presentations (e.g. treatment of parapharyngeal abscess)

It is important to note that national randomised control trial is underway comparing surgery versus conservative management for recurrent tonsillitis in adults in underway which may warrant review of this guidance in the near future.

6.4 Adult Snoring Surgery (in the absence of Obstructive Sleep Apnoea)

Status- Not Routinely Commissioned[3]

In two systematic reviews of 72 primary research studies, there was no evidence that surgery to the palate to improve snoring provides any additional benefit compared to non-surgical treatments. The surgery has up to 16% risk of severe complications (bleeding, airway compromise, death). Therefore it is no longer commissioned. A number of alternatives to surgery can improve snoring. These include lifestyle changes (weight loss, smoking cessation and reducing alcohol intake) and medical treatment of nasal congestion.

Alternative Treatments There are a number of alternatives to surgery that can improve the symptom of snoring. These include:

- Weight loss
- Stopping smoking
- Reducing alcohol intake
- Medical treatment of nasal congestion (rhinitis)
- Mouth splints (to move jaw forward when sleeping)

7 Equality Impact Assessment (EIA)

This document has been assessed, using the EIA toolkit, to ensure consideration has been given to the actual or potential impacts on staff, certain communities or population groups, appropriate action has been taken to mitigate or eliminate the negative impacts and maximise the positive impacts and that the and that the implementation plans are appropriate and proportionate.

[33] https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf (accessed 05/02/2019)

Include summary of key findings/actions identified as a result of carrying out the EIA. The full EIA is attached as Appendix A.

8 Implications and Associated Risks

This policy and supporting frameworks set evidence based boundaries to interventions available on the NHS. It may conflict with expectations of individual patients and clinicians.

9 Education and Training Requirements

Members of the panels will undergo training at least every three years, particularly in relation to the legal precedents around IFRs. Effective policy dissemination is required for local clinicians.

10 Monitoring Compliance and Effectiveness

Each IFR panel will maintain an accurate database of cases approved and rejected, to enable consideration of amendments to future commissioning intentions and to ensure consistency in the application of the CCGs in Leeds Commissioning Policies.

The financial impact of approvals outside of existing Service Level Agreements will be monitored to ensure the Leeds CCGs identify expenditure and ensure appropriate value for money. Member Practice clinicians need to be aware that all referrals will ultimately be a call on their own CCG budgets.

11 Associated Documentation

This policy must be read in conjunction with the underpinning Leeds CCG decision making frameworks.

12 References

Appendices

A: Equality Impact Assessment

Title of policy	Ear Nose and Throat Policy	
Names and roles of people completing the assessment	Fiona Day Consultant in Public Health Medicine, Helen Lewis, Head of Acute Provider Commissioning	
Date assessment started/completed	18.04.18	18.04.18

1. Outline	
Give a brief summary of the policy	The purpose of the commissioning policy is to enable officers of the Leeds CCG to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCG. This policy relates to requests for Ear Nose and Throat procedures.
What outcomes do you want to achieve	We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness.

2. Evidence, data or research	
Give details of evidence, data or research used to inform the analysis of impact	See list of references

3. Consultation, engagement	
Give details of all consultation and engagement activities used to inform the analysis of impact	Discussion with clinicians and patient representatives on the principles of decision making. Discussion with patient leaders relating to changes in the content of the policy and advice on proportionate engagement. The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing

	assurance. No concerns were raised with regard to the policy. Local clinical commissioning and clinical providers have had the opportunity to comment on the draft policies.

4. Analysis of impact			
This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to; eliminate unlawful discrimination; advance equality of opportunity; foster good relations			
	Are there any likely impacts? **Are any groups going to be affected differently?** **Please describe.**	**Are these negative or positive?**	**What action will be taken to address any negative impacts or enhance positive ones?**
Age	Yes children		
Carers	Some interventions for children	Positive	Some of the interventions a carer may think the criteria for surgery are harsh ie discomfort/repeated occurrences etc. but the evidence base outweighs the thresholds.
Disability	Patients with a disability due to hearing loss	Positive	Evidence based interventions and thresholds applied equally across the population according to patient need.
Sex	No		
Race	No		
Religion or belief	No		
Sexual orientation	No		
Gender reassignment	No		
Pregnancy and maternity	No		
Marriage and civil	No		

partnership			
Other relevant group	No		
If any negative/positive impacts were identified are they valid, legal and/or justifiable? **Please detail.**		Impacts are considered to be positive and to enhance equity of access.	

5. Monitoring, Review and Publication			
How will you review/monitor the impact and effectiveness of your actions	Annual report of IFR activity reported through relevant committees to Governing Bodies of the 3 CCGs. A limited equity audit is undertaken as part of this. Complaints and appeals monitoring.		
Lead Officer	Dr Simon Stockill	**Review date:**	December 2019

6.Sign off			
Lead Officer	Dr Simon Stockill, Medical Director		
Medical Director		**Date approved:**	9 May 2018

B Policy Consultation Process:

Title of document	Ear, Nose and Throat Commissioning Policies
Author	F Day, M Everitt
New / Revised document	Revised
Lists of persons involved in developing the policy List of persons involved in the consultation process:	F Day Consultant in Public Health Medicine, M Everitt Public Health Registrar, Leeds City Council Donald Dewar, Consultant Plastic Surgeon, LTHT See appendix A

C Version Control Sheet

Version	Date	Author	Status	Comment
V1	13.7.16	F Day, M Everitt	Draft	Addition of 'significant external deformity' to septorhinoplasty criteria; on advice from consultant plastic surgeon
V2	18.4.18	F Day	Amended	Addition of ear wax management section; amendments to reflect 3 CCGs into one.
Updated policy 2019-22	13.02.19	F Day	Updated	Addition of section 6.4 Snoring and updated 6.1.4 (grommets) and 6.3 (tonsillectomy) in line with NHS England Evidence Based Interventions : Response to the public consultation and next steps (28th November 2018) 6.1.3 addition of physical characteristics required for pinnaplasty in children