NHS
Leeds
Clinical Commissioning Group

General Surgery Commissioning Policies

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Ratified by:	NHS Leeds Clinical Commissioning Group Quality and Performance Committee – 13 March 2019
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Name of responsible committee/individual:	Dr Simon Stockill Medical Director, NHS Leeds CCG Governing Body
Date issued:	March 2019
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Target audience:	Primary and secondary care clinicians, individual funding request panels, and the public
Document History:	Leeds CCG Cosmetic Exceptions and Exclusions Policy Feb 2014 Leeds CCG Targeted Interventions Policy Feb 2014 Leeds CCG General Surgery Policy 2017-19

Produced on behalf of NHS Leeds West Clinical Commissioning Group, NHS Leeds North Clinical Commissioning Group and NHS Leeds South and East 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 :

This policy relates specifically to general surgery commissioning policies (varicose veins, haemorrhoidectomy, groin hernia, gallstones).

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:

This policy relates specifically to general surgery commissioning policies (varicose veins, haemorrhoidectomy, groin hernia, gallstones).

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 Asymptomatic Gallstones Removal
Status: not routinely commissioned

Gallstones occur when hard fatty or mineral deposits form in the gallbladder. They are common (15% of the adult population) and most of these do not experience any symptoms. If the stones cause irritation of the gallbladder or cause a blockage this can result in symptoms such as pain and infections. If they are causing symptoms it is sometimes best to remove the gallbladder to prevent serious complications such as cholecystitis and pancreatitis.

This policy refers to **asymptomatic gallstones only**. See definitions below of symptomatic and asymptomatic gallstones.

Symptomatic gallstones/ symptomatic common bile duct stones: Stones found on gallbladder imaging, regardless of whether symptoms are being experienced currently or whether they occurred sometime in the 12 months before diagnosis.

Asymptomatic gallstones/ asymptomatic common bile duct stones: Stones that are found incidentally, as a result of imaging investigations unrelated to gallstone disease in people who have been completely symptom free for at least 12 months before diagnosis.

No interventions aimed at treating gallstones (including cholecystectomy) will be routinely commissioned for asymptomatic gallstones found in a normal gallbladder with a normal biliary tree

This is in line with guidance issued by NICE within Clinical Guidelines 188, Gallstone disease: diagnosis and initial management

NICE Guidelines (CG188) Gallstone disease: diagnosis and initial management (accessed 14/7/16)

This is also in line with commissioning guidance issued by the Royal College of Surgeons in Commissioning Guide: Gallstone Disease 2013

Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland and Royal College of Surgeons (2013) Commissioning guide: Gallstone disease (accessed 14/7/16)

Patient decision aid:

Gallstones Rightcare PDA

6.2 Groin Hernia Repair

Status: routinely commissioned in specific circumstances

A hernia is the protrusion of an internal part of the body through the muscle or surrounding tissue wall. They can occur in many locations throughout the body. This policy refers to those hernias which occur in the groin; these fall into two types:

- Inguinal hernia: the protrusion of part of the intestines or internal fat into the inguinal canal – this is a channel through the abdominal wall and into the groin containing the blood vessels and nerves supplying the testicle in males and in females containing nerves and ligaments supporting the uterus. This channel is a natural area of weakness, particularly for men. Inguinal hernias are more common in men than women.
- Femoral hernia: the protrusion of part of the intestine or internal fat through the femoral canal - a channel connecting the abdomen and the thigh through which large blood vessels pass. Femoral hernias are linked to a higher rate of complications including obstruction of the bowel and strangulation (trapping of a section of bowel which then becomes ischaemic due to reduced blood supply).

Please follow the guidance below as recommended by the Royal College of Surgeons, British Hernia Society and the Association of Surgeons of Great Britain and Ireland.

<u>Primary Care:</u>

Conservative management in primary care only is appropriate for the following patients:

Patients with occult or asymptomatic or minimally symptomatic primary or recurrent inguinal hernias
AND
Have a significant comorbidity (i.e. would be considered a 3 or 4 on the ASA scale)
AND
Do not want to have a surgical repair after being informed appropriately about the procedure

All other patients should be referred to a secondary care provider for assessment.

For further guidance regarding the management of groin hernias in primary care including information about appropriate speed of referral please see the Groin Hernia Guidelines published by the Association of Great Britain and Ireland (2013)

<u>Secondary Care</u>

Surgical repair should be offered to patients with a symptomatic inguinal hernia.

Surgical repair is recommended for patients with a femoral hernia

Surgery is not routinely commissioned for patients who currently have an asymptomatic inguinal hernia.

It is recognised that though surgery for hernias that are asymptomatic is not commissioned there is a high likelihood the patient will ultimately develop symptoms and require surgical repair.

Patient decision aid:

Inguinal Hernia Rightcare PDA

6.3 Interventional Management of Varicose Veins

Status: routinely commissioned in specific circumstances[1]

1.1 Intervention in terms of, endovenous thermal (laser ablation, and radiofrequency ablation), ultrasound guided foam sclerotherapy, open surgery (ligation and stripping) are all cost effective treatments for managing symptomatic varicose veins compared to no treatment or the use of compression hosiery. For truncal ablation there is a treatment hierarchy based on the cost effectiveness and suitability, which is endothermal ablation then ultrasound guided foam, then conventional surgery.

1.2 Refer people to a vascular service if they have any of the following;*1.* Symptomatic * primary or recurrent varicose veins. *2.* Lower−limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency. *3.* Superficial vein thrombophlebitis (characterised by the appearance of hard, painful veins) and suspected venous incompetence. *4.* A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks). *5.* A healed venous leg ulcer.

**Symptomatic: "Veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching)." For patients whose veins are purely cosmetic and are not associated with any symptoms do not refer for NHS treatment.*

1.3 Refer people with bleeding varicose veins to a vascular service immediately.

1.4 Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

For further information, please see:
- https://www.nice.org.uk/guidance/qs67
- https://www.guidelinesinpractice.co.uk/nice-referral-advice-11-varicose-veins/300594.article
- https://www.nice.org.uk/guidance/cg168

6.4 Haemorrhoid Excision
Status: routinely commissioned in specific circumstances[2]

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[1] https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf (accessed 05.02.19)

[2] https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf (accessed 05.02.19)

Often haemorrhiods (especially early stage haemorrhoids) can be treated by simple measures such as eating more fibre or drinking more water. If these treatments are unsuccessful many patients will respond to outpatient treatment in the form of banding or perhaps injection.

Surgical treatment should only be considered for those that do not respond to these non-operative measures or if the haemorrhoids are more severe, specifically:

- Recurrent grade 3 or grade 4 combined internal/external haemorrhoids with persistent pain or bleeding; or
- Irreducible and large external haemorrhoids In cases where there is significant rectal bleeding the patient should be examined internally by a specialist.

6.5 Anal Skin tags

Refer to general cosmetics policy.

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.

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 CCGs decision making frameworks.

12 Additional References

Groin Hernia

http://www.nhs.uk/conditions/Inguinalherniarepair/Pages/Whatisitpage.aspx (accessed 9/5/16)

http://www.nhs.uk/conditions/primaryrepairoffemoralhernia/Pages/Introduction.aspx (accessed 9/5/16)

Association of Surgeons of Great Britain and Ireland and the Royal College of Surgeons (2013) Commissioning Guide: Groin Hernia

Association of Surgeons of Great Britain and Ireland (2013) Groin Hernia Guidelines

Haemorrhoid Excision

http://www.nhs.uk/Conditions/Haemorrhoids/Pages/What-is-it-page.aspx (accessed 3/5/16)

http://cks.nice.org.uk/haemorrhoids#!scenario (accessed 14/7/16)

Varicose Veins

NICE Guidelines (CG168) Varicose veins: diagnosis and management

NICE Pathway: Varicose veins in the legs

Other Guidance:

NICE Quality Standard (QS67) Varicose veins in the legs

NICE Interventional Procedure Guidance (IPG8) Radiofrequency ablation of varicose veins

NICE Interventional Procedure Guidance (IPG52) Endovenous laser treatment of the long saphenous vein

NICE Interventional Procedure Guidance (IPG440) Ultra-sound guided foam sclerotherapy for varicose veins

Asymptomatic Gallstones

NICE Clinical Guidelines 188, Gallstone disease: diagnosis and initial management

Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland and Royal College of Surgeons (2013) Commissioning guide: Gallstone disease

Appendices

A Equality Impact Assessment

Title of policy	General Surgery 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	26.6.16	25.7.16

1. Outline	
Give a brief summary of the policy	The purpose of the commissioning policy is to enable officers of the Leeds CCGs 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 CCGs. This policy relates to requests for general surgery.
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	No		
Carers	No		
Disability	No		
Sex	No		
Race	No		
Religion or belief	No		
Sexual orientation	No		
Gender reassignment	No		
Pregnancy and maternity	No		
Marriage and civil partnership	No		
Other relevant	No		

group			
If any negative/positive impacts were identified are they valid, legal and/or justifiable? **Please detail.**			

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	Simon Stockill	**Review date:**	Dec 2019

6.Sign off			
Lead Officer			
Director on behalf of the 3 Leeds CCG Medical Directors	Dr Simon Stockill, Medical Director, Leeds West CCG	**Date approved:**	24.8.16

B Policy Consultation Process:

Title of document	General Surgery Commissioning Policies
Author	F Day, M Everitt, Public Health Leeds City Council
New / Revised document	New
Lists of persons involved in developing the policy List of persons involved in the consultation process:	F Day Consultant in Public Health Medicine, Leeds City Council See appendix A

C Version Control Sheet

Version	Date	Author	Status	Comment
1.0	14.7.16	F Day, M Everitt	Draft	New hernia and gallstones policies in line with NICE;
2.0	5.2.19	F Day	updated	Updated haemorrhoids and varicose veins in line with NHSE Evidence Based Interventions : Response to the public consultation and next steps (November 28th 2018)