

Policy for Cholecystectomy for Asymptomatic Gallstones

Category

Not routinely commissioned

CHOLECYSTECTOMY FOR ASYMPTOMATIC GALLSTONES

Gallstones are small stones usually made of cholesterol that form in the gallbladder. In most cases they do not cause any symptoms i.e. they are asymptomatic.

Cholecystectomy is the surgical removal of the gallbladder, this is not usually indicated in patients with asymptomatic gallstones.

Note: Patients with suspected gallbladder carcinoma or severe complications should be referred/treated immediately, without delay.

Cholecystectomy for Asymptomatic Gallstones is not routinely commissioned.

This is because the majority of people with gallbladder stones remain asymptomatic (without symptom) and require no treatment. If you do not have any symptoms, a policy of 'active monitoring' is often recommended. This means you won't receive immediate treatment, but you should let your GP know if you notice any symptoms. As a general rule, the longer you go without symptoms, the less likely it is that your condition will get worse.

This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

For patients with symptoms follow the Royal College of Surgeons guidance detailed below.

RCS Commissioning Guide: Gallstone Disease

High value care pathway for gallstone disease

Management

- Patients with an incidental finding of stones in an otherwise normal gallbladder require no further investigation or referral.
- Most patients with symptomatic gallstones present with a self-limiting attack of pain that lasts for hours only. This can often be controlled successfully in primary care with appropriate analgesia, avoiding the requirement for emergency admission. When pain cannot be managed or if the patient is otherwise unwell (eg sepsis), he or she should be referred to hospital as an emergency.
- Further episodes of biliary pain can be prevented in around 30% of patients by adopting a low fat diet. Fat in the stomach releases cholecystokinin, which precipitates (brings about) gallbladder contraction and might result in biliary pain.
- Patients with suspected acute cholecystitis, cholangitis or acute pancreatitis should be referred to hospital as an emergency.
- There is no evidence to support the use of hyoscine or proton pump inhibitors in the management of gallbladder symptoms. Antibiotics should be reserved for patients with signs of sepsis.
- There is no evidence of benefit from the use of non-surgical treatments in the definitive management of gallbladder stones (e.g. gallstone dissolution therapies, ursodeoxycholic acid or extracorporeal lithotripsy).

Best practice referral guidelines

- Epigastric or right upper quadrant pain, frequently radiating to the back, lasting for several minutes to hours (often occurring at night) suggests symptomatic gallstones. These patients should have liver function tests checked and be referred for ultrasonography.
- Confirmation of symptomatic gallstones should result in a discussion of the merits of a referral to a surgical service regularly performing cholecystectomies.
- Following treatment for CBD stones with endoscopic retrograde cholangiopancreatography (ERCP) and sphincterotomy, removal of the gallbladder should be considered in all patients. However, in patients with significant co-morbidities (other risk factors alongside the primary problem), the risks of surgery may outweigh the benefits

Treatment is available for patients that are at high risk of the following:

- Patients with diabetes mellitus/transplant recipient patients/patients with cirrhosis who have been managed conservatively and subsequently develop symptoms
- Where there is clear evidence of patients being at risk of gallbladder carcinoma
- Confirmed episode of Gallstone induced pancreatitis
- Confirmed episode of Cholecystiti
- Episode of obstructive jaundice caused by biliary calculi.

Guidance

NICE CG 188 - Gallstone disease: diagnosis and initial management (2014)

Weblink:

<http://www.nice.org.uk/guidance/cg188/resources/guidance-gallstone-disease-pdf>

Royal College of Surgeons - Commissioning Guide: Gallstone disease and Best Practice Referral

Guideline (2013).

Weblink:

<https://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/gallstones/view>

NHS Choices – Gallstones

Weblink:

<http://www.nhs.uk/Conditions/Gallstones/Pages/Introduction.aspx>

TREATMENT POLICIES – FURTHER INFORMATION

The purpose of this document is to describe the access and exclusion criteria which the CCGs listed below will apply to Treatment Policies.

The term ‘Treatment Policies’, refers to procedures and treatments that are of value, but only in the right clinical circumstances.

The main objective for having treatment policies is to ensure that:

- Patients receive appropriate health treatments in the right place and at the right time;
- Treatments with no or a very limited evidence base are not used; and
- Treatments with minimal health gain are restricted.

BACKGROUND

The following Clinical Commissioning Groups (CCG) and their respective Local Authority Public Health Commissioners have worked collaboratively to develop this harmonised core set of commissioning policies:

- NHS Birmingham CrossCity CCG
- NHS Birmingham South Central CCG
- NHS Sandwell and West Birmingham CCG
- NHS Solihull CCG
- NHS Walsall CCG
- NHS Wolverhampton CCG

The policy aims to improve consistency by bringing together the different policies across Birmingham, Solihull and the Black Country into one common set. This helps us to stop variation in access to NHS services in different areas (which is sometimes called ‘postcode lottery’ in the media) and allow fair and equitable treatment for all local patients.

CCGs have limited budgets; these are used to commission healthcare that meets the reasonable requirements of its patients, subject to the CCG staying within the budget it has been allocated. By using these policies, we can prioritise resources using the best evidence about what is clinically effective, to provide the greatest proven health gain for the whole of the CCG’s population. Our intention is to ensure access to NHS funding is equal and fair, whilst considering the needs of the overall population and evidence of clinical and cost effectiveness.

In cases of diagnostic uncertainty, the scope of this policy does not exclude the clinician’s right to seek specialist advice. This advice can be accessed through a variety of different mediums and can include both face to face specialist contact as well as different models of consultant and specialist nurse advice and guidance virtually.

We recognise there may be exceptional circumstances where it is clinically appropriate to fund each of the procedures listed in this policy and these will be considered on a case-by-case basis. Funding for cases where either; a) the clinical threshold criteria is not met, or b) the procedure is Not routinely commissioned, will be considered by the CCGs following application to the CCG’s Individual Funding Request Panel, whereby the IFR process will be applied.

This position is supported by each CCG's Ethical Framework which can be found on the respective CCG website.

PRINCIPLES

Commissioning decisions by CCG Commissioners are made in accordance with the commissioning principles set out below, and in the Birmingham, Black Country and Solihull CCGs' Individual Funding Request Policy:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community;
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance; and
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered.

LIFESTYLE FACTORS AND SURGERY

Lifestyle factors can have an impact on the functional results of some elective surgery. In particular, smoking is well known to affect the outcomes of some foot and ankle procedures.

In addition, many studies have shown that the rates of postoperative complications and length of stay are higher in patients who are overweight or who smoke.

Therefore, to ensure optimal outcomes, all patients who smoke or have a body mass index of 35 or greater and are being considered for referral to secondary care, should be able to access CCG and Local Authority Public Health commissioned smoking cessation and weight reduction management services prior to surgery.

Patient engagement with these "preventive services" may influence the immediate outcome of surgery. While failure to quit smoking or lose weight will not be a contraindication for surgery, GPs and Surgeons should ensure patients are fully informed of the risks associated with the procedure in the context of their lifestyle.

PSYCHOLOGICAL FACTORS AND SURGERY

Commissioners acknowledge that there is a psychological dimension for patients in seeking or considering the option of treatment and surgery. However, as there are no universally accepted and

objective measures of psychological distress, such factors are not taken into account in any policy clinical thresholds. Nevertheless, there always remains the option of an application to demonstrate clinical exceptionalality through IFR.

IMPLEMENTATION

Commissioners, GPs, service providers and clinical staff treating registered patients of the CCGs are expected to implement this policy. When procedures are undertaken on the basis of meeting the criteria specified within the policy, this should be clearly documented within the clinical notes. Failure to do so will be considered by the CCGs as lack of compliance.

Patients with problems or conditions that might require treatments included in this policy should be referred to a consultant or specialist only;

- After a clinical assessment is made by the GP or Consultant; **AND**
- The patient meets all the criteria set out in the policy.

GPs wishing to seek a specialist opinion for patients who meet the above criteria should ensure the essential clinical information is included in the referral letter confirming the patient has been assessed in line with this policy.

GPs, Consultants in secondary care and provider finance departments need to be aware that the CCG will not pay for the procedures listed in this policy unless the patient meets the criteria outlined in this policy.

The CCGs recognise there will be exceptional, individual or clinical circumstances when funding for treatments designated as low priority will be appropriate.

Where a treatment is either not routinely commissioned, or the patient does not meet the specified clinical criteria, this means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Individual Funding Requests should **only** be sent to the respective NHS.net account as below. Guidance regarding IFRs and an application form can be found on the CCGs websites.

IFR contact information follows, however please refer to the CCG IFR policy for more information.

Individual Funding Request Case Manager, Floor Two, Kingston House,
438 High Street, West Bromwich, West Midlands, B70 9LD

Telephone: 0121 612 1660

Email addresses for Individual Funding Request teams at CCGs

(Ctrl+Click required address to send email):

- Birmingham CrossCity CCG ifr.bcccg@nhs.net
- Birmingham South Central CCG ifr.bsc@nhs.net
- Solihull CCG ifr.solihull@nhs.net
- NHS Sandwell and West Birmingham CCG ifr.swb@nhs.net
- NHS Walsall CCG ifr.walsall@nhs.net
- NHS Wolverhampton CCG ifr.wolv@nhs.net

MONITORING AND REVIEW

This policy will be subject to continued monitoring using a mix of the following approaches:

- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding clinical and cost effectiveness.

COPIES OF THIS POLICY

Electronic copies of this policy can be found on the websites of the respective CCGs. Alternatively, you may contact the CCG and ask for a copy.

SCOPE

The following is a summary of all treatment policies.

Each policy is categorised as either 'Not routinely commissioned' or 'restricted' these are defined as follows:

- **Not routinely commissioned** – This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
- **Restricted** – This means CCG will fund the treatment **if** the patient meets the stated clinical threshold for care.

Policy	Treatment	Category
Adenoidectomy		Restricted
Cosmetic Surgery	Abdominoplasty / Apronectomy	Not routinely commissioned
Cosmetic Surgery	Thigh Lift, Buttock Lift and Arm Lift, Excision of Redundant Skin or Fat	Not routinely commissioned
Cosmetic Surgery	Liposuction	Not routinely commissioned
Cosmetic Surgery	Breast Augmentation a) Non breast cancer b) Breast cancer	Not routinely commissioned Restricted
Cosmetic Surgery	Breast Reduction	Restricted
Cosmetic Surgery	Mastopexy (Breast Lift)	Not routinely commissioned
Cosmetic Surgery	Inverted Nipple Correction	Not routinely commissioned
Cosmetic Surgery	Gynaecomastia (Male Breast Reduction)	Not routinely commissioned
Cosmetic Surgery	Labiaplasty	Restricted
Cosmetic Surgery	Vaginoplasty	Restricted
Cosmetic Surgery	Pinnaplasty	Not routinely commissioned
Cosmetic Surgery	Repair of Ear Lobes	Not routinely commissioned

Policy	Treatment	Category
Cosmetic Surgery	Rhinoplasty	Restricted
Cosmetic Surgery	Face Lift or Brow Lift (Rhytidectomy)	Restricted
Cosmetic Surgery	Hair Depilation (Hirsutism)	Restricted
Cosmetic Surgery	Alopecia (Hair Loss)	Not routinely commissioned
Cosmetic Surgery	Removal of Tattoos / Surgical correction of body piercings and correction of respective problems	Not routinely commissioned
Cosmetic Surgery	Removal of Lipomata	Restricted
Cosmetic Surgery	Removal of Benign or Congenital Skin Lesions	Restricted
Cosmetic Surgery	Medical and Surgical Treatment of Scars and Keloids	Not routinely commissioned
Cosmetic Surgery	Botulinum Toxin Injection for the Ageing Face	Not routinely commissioned
Cosmetic Surgery	Treatment for Viral Warts	Restricted
Cosmetic Surgery	Thread / Telangiectasis / Reticular Veins	Not routinely commissioned
Cosmetic Surgery	Rhinophyma	Not routinely commissioned
Cosmetic Surgery	Resurfacing Procedures: Dermabrasion, Chemical Peels and Laser Treatment	Not routinely commissioned
Cosmetic Surgery	Other Cosmetic Procedures	Not routinely commissioned
Cosmetic Surgery	Revision of Previous Cosmetic Surgery Procedures	Not routinely commissioned
Non Specific, Specific and Chronic Back Pain		Restricted
Botulinum Toxin for Hyperhidrosis		Not routinely commissioned
Cataracts		Restricted
Cholecystectomy for Asymptomatic Gallstones		Not routinely commissioned
Male Circumcision		Restricted
Dilation and Curettage (D&C) for Menorrhagia		Not routinely commissioned
Eyelid Surgery (Upper and Lower) - Blepharoplasty		Restricted
Ganglion		Restricted
Grommets		Restricted
Haemorrhoidectomy		Restricted
Hip Replacement Surgery		Restricted
Hysterectomy for Heavy Menstrual Bleeding		Restricted
Hysteroscopy for Menorrhagia		Not routinely commissioned
Groin Hernia Repair		Restricted
Knee Replacement Surgery		Restricted
Penile Implants		Not routinely commissioned
Tonsillectomy		Restricted
Trigger Finger		Restricted
Varicose Veins		Restricted

GLOSSARY OF TERMS

TERM	MEANING
Abdominoplasty/Apronectomy	A procedure to reduce excess skin and fat, improve abdominal contours and scars, and tighten muscles. This is sometimes called a 'tummy tuck'.
Active treatment	Treatment and care to manage a particular disease / condition, e.g. cancer treatment, renal dialysis.
Adenoidectomy	A procedure to remove the adenoids – lumps of tissue at the back of the nose.
Aesthetics	These are procedures which relate to cosmetic procedures which are intended to restore or improve a person's appearance.
Alopecia	Hair loss.
Analgesics	Painkillers.
Asymptomatic	Without symptoms.
Augmentation	Increasing in size, for example breast augmentation.
BCH	Birmingham Children's Hospital NHS Foundation Trust.
BCHC	Birmingham Community Healthcare NHS Foundation Trust.
Benign	Does not invade surrounding tissue or spread to other parts of the body; it is not a cancer.
Binocular vision	Vision in both eyes.
Body Mass Index (BMI)	Body Mass Index - a measure that adults can use to see if they are a healthy weight for their height.
BWH	Birmingham Women's Hospital NHS Foundation Trust
Cataract	When the lens of an eye becomes cloudy and affects vision
CCG	Clinical Commissioning Group. CCGs are groups of General Practices that work together to plan and design local health services in England. They do this by 'commissioning' or buying health and care services.
Cholecystectomy	Removal of the gall bladder.
Chronic	Persistent
Co-morbidities	Other risk factors alongside the primary problem.
Congenital	Present from birth
Conservative treatment	The management and care of a patient by less invasive means; these are usually non-surgical
Depilation	Removal. For example hair depilation.
DOH	Department of Health
Eligibility/Threshold	Whether someone qualifies. In this case, the minimum criteria to access a procedure.
Exceptional clinical circumstances	A patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients, with the same medical condition and at the same stage of progression as the patient.
Functional health problem/difficulty/impairment	Difficulty in performing, or requiring assistance from another to perform, one or more activities of daily living.
Ganglion	A non-cancerous fluid filled lump.
GP	General Practitioner.
Gynaecomastia	Benign enlargement of the male breast.

TERM	MEANING
Haemorrhoidectomy	A procedure to cut away haemorrhoids, sometimes called piles.
HEFT	Heart of England NHS Foundation Trust.
Histology	The structure of cells or tissue under a microscope.
Hyperhidrosis	Excess sweating.
Hysteroscopy	A hysteroscopy is a procedure used to examine the inside of the womb (uterus) using a hysteroscope (a narrow telescope with a light and camera at the end. Images are sent to a monitor so your doctor or specialist nurse can see inside your womb).
Individual Funding Request (IFR)	A request received from a provider or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.
Irreducible	Unable to be reduced.
Labiaplasty	A procedure to reduce and/or reshape the labia.
Lipomata	Fat deposits under the skin.
Liposuction	A procedure using a suction technique to remove fat from specific areas of the body.
Malignant/malignancy	Harmful.
Mastopexy	A reconstructive procedure to lift the breast.
Menorrhagia	Abnormally heavy or prolonged bleeding at menstruation
Monocular vision	Vision in one eye only.
Multi-disciplinary	Involving several professional specialisms for example in a Multi-disciplinary team (MDT).
NICE guidance	The guidance published by the National Institute for Health and Care Excellence.
Not routinely commissioned (a procedure)	This means the CCG will <u>only</u> fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
NSAIDS	Non-steroidal anti-inflammatory drugs – medication that reduces pain, fever and inflammation.
Paediatric(ian)	Medical care concerning infants, children and adolescents usually under 18.
Pathology/pathological	The way a disease or condition works or behaves. This may for example include examination of bodily fluids or tissue e.g. blood testing.
PCT	Primary Care Trust (PCTs were abolished on 31 March 2013, and replaced by Clinical Commissioning Groups).
Pinnaplasty	A procedure to pin or correct deformities the ear
PLCV	Procedures of Lower Clinical Value; routine procedures that are of value, but only in the right circumstances.
Precipitates	Brings about/triggers.
Primary care	a patient's first point of interaction with NHS services e.g. a GP surgery.
Prophylactic	Preventative or prevention.
Rationale	Explanation of the reason why.
Restricted (a procedure)	This means CCG will fund the treatment <u>if</u> the patient meets the stated clinical threshold for care.
Rhinophyma	A condition causing development of a large, bulbous, ruddy

TERM	MEANING
	(red coloured), nose.
Rhinoplasty	A procedure to shape the size and/or shape of the nose.
Rhytidectomy	A procedure to restore facial appearance or function. These are sometime called face or brow lifts.
Secondary care	Services provided by medical specialists, who generally do not have the first contact with a patient e.g. hospital services.
Stakeholders	Individuals, groups or organisations who are or will be affected by this consultation, e.g. patients who currently use the service, carers, specific patient groups, etc.
Symptomatic	Something causing or exhibiting symptoms.
Tonsillectomy	A procedure to remove the tonsils.
UHB	University Hospital Birmingham NHS Foundation Trust.
Vaginoplasty	A procedure to reconstruct the vaginal canal.