NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Gallstones (Asymptomatic), Surgical Management

Category 1 Intervention - Not routinely commissioned -

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Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
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Document control:		
Date:	**Version Number:**	**Section and Description of Change**
April 2023	1	Policy ratified by Cheshire & Merseyside ICB

1. Introduction

1.1 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

1.2 This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined in Appendix 1.

1.3 At the time of publication, the evidence presented per procedure/treatment was the most current available.

2. Purpose

2.1 This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

3. Policy statement

3.1 Surgical removal of asymptomatic gallstones is not routinely commissioned.

4. Exclusions

4.1 None.

5. Rationale

5.1 Gallstones are extremely common, and the majority of people remain asymptomatic without the need for further treatment.

5.2 Surgical management is not without risk and is usually unnecessary.

6. Underpinning evidence

6.1 Gallstone disease occurs when hard fatty or mineral deposits (gallstones) form in the gallbladder. Approximately 15% of the adult population are thought to have gallstone disease, and most of these people experience no symptoms.

6.2 NICE defines asymptomatic gallstones thus: 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.

6.3 For a small proportion of people with gallstone disease, the stones irritate the gallbladder or block part of the biliary system, and this can cause symptoms such as pain, infection and inflammation. If these symptoms are left untreated, gallstones can cause more serious and, in some cases, life-threatening conditions such as cholecystitis, cholangitis, pancreatitis and jaundice.

6.4 There is variation in how gallstone disease is managed. Some people with symptomless gallstone disease are offered treatment to prevent symptoms developing in the future, whereas others are offered a watch and wait approach. When people experience symptoms of gallstone disease, they often need surgery to remove their gallbladder. There is uncertainty about the best way of treating gallstone disease. In addition, if surgery is appropriate there is uncertainty about whether it should be performed as soon as possible after a gallstones attack or delayed until any infection and inflammation has subsided.

6.5 In its 2013 commissioning guide on gallstone disease, the Royal College of Surgeons suggest that the majority of people with gallbladder stones remain asymptomatic and require no treatment. Patients with symptomatic gallstones may require surgical removal of the gallbladder. NICE recommends "Reassure people with asymptomatic gallbladder stones found in a normal gallbladder and normal biliary tree that they do not need treatment unless they develop symptoms."

REFERENCES

1. Gallstone disease: diagnosis and management. NICE CG188, 29th October 2014. https://www.nice.org.uk/guidance/cg188/chapter/1-Recommendations,
2. Commissioning Guide: Gallstone disease. The Royal College of surgeons, London, 2013. https://www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/gallstones-commissioning-guide/

7. Force

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

8. Coding

8.1 Office of Population Censuses and Surveys (OPCS)

These are all the potential procedures which could be done for gall stones. Many of them would be entirely appropriate, but we have no way of knowing which are asymptomatic.

J181 Total cholecystectomy and excision of surrounding tissue
J182 Total cholecystectomy and exploration of common bile duct
J183 Total cholecystectomy NEC
J184 Partial cholecystectomy and exploration of common bile duct
J185 Partial cholecystectomy NEC
J188 Other specified excision of gall bladder
J189 Unspecified excision of gall bladder
J211 Open removal of calculus from gall bladder
J233 Exploration of gall bladder
J238 Other specified other open operations on gall bladder
J239 Unspecified other open operations on gall bladder
J24 Therapeutic percutaneous operations on gall bladder
J242 Percutaneous fragmentation of calculus in gall bladder
J243 Percutaneous dissolution therapy to calculus in gall bladder
J248 Other specified therapeutic percutaneous operations on gall bladder
J249 Unspecified therapeutic percutaneous operations on gall bladder
J268 Other specified other operations on gall bladder
J269 Unspecified other operations on gall bladder
J331 Open removal of calculus from bile duct and drainage of bile duct
J332 Open removal of calculus from bile duct NEC

8.2 International classification of diseases (ICD-10)
K80 is cholelithiasis which is gallstones, but ICDs are about condition they are causing, e.g. K80.0 acute cholecystitis, K80.1 chronic cholecystitis, etc. - if they are asymptomatic, they are not causing a condition, however any healthcare establishment doing a procedure would put a diagnosis code to it. K80.8 is gallstone, specified, not elsewhere classified.

9. Monitoring And Review

9.1 This policy may 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

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

10. Quality and Equality Analysis

10.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

Appendix 1 - Core Objectives and Principles

Objectives

The main objective for having healthcare commissioning policies is to ensure that:

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

Principles

This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

- Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
- Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
- Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
- Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
- Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
- Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
- Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
- NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

Cosmetic Surgery

Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

A summary of Cosmetic Surgery is provided by NHS Choices. Weblink:
http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and
http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

Diagnostic Procedures

Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

Clinical Trials

The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

Clinical Exceptionality

If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy.