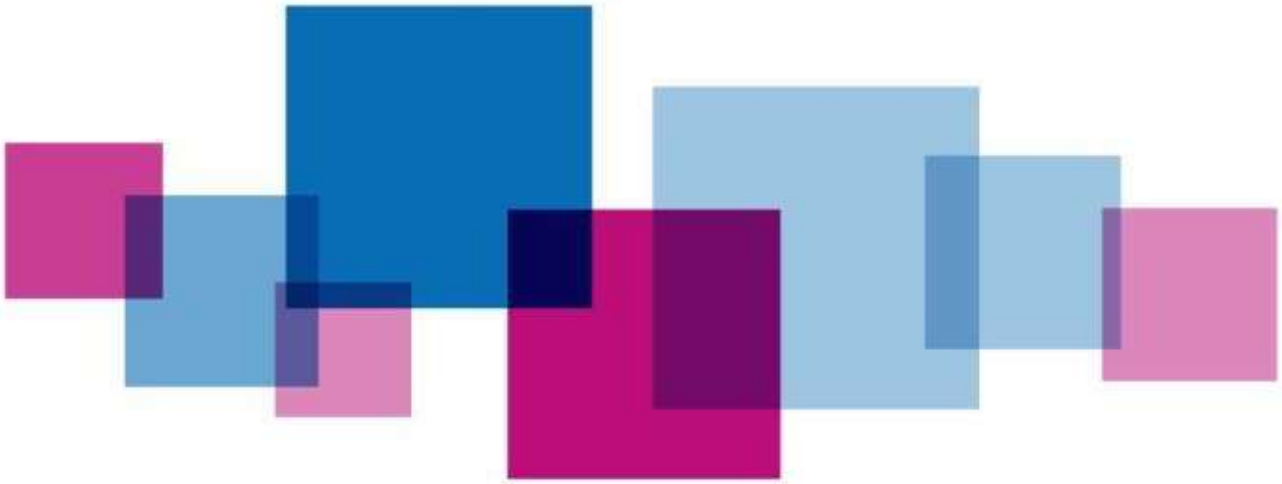
Bristol, North Somerset
and South Gloucestershire
Integrated Care Board

Commissioning Policy

Gallbladder Removal in Adult Patients – Over 18 Years

Criteria Based Access



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Shaping better health

Document Control

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Version Control

Version	Date	Reviewer	Comment
1819.1.00	01/06/2018	IFR Manager	1. Rebranding 2. Changes to Symptomatic criteria wording to assist administration understanding presentation of symptoms 3. Change to Asymptomatic in line with clinical feedback and guidance
1819.1.01	25/06/2018	IFR Coordinator	Change of name from "Laparoscopic Cholecystectomy for Gallstones in Adults" Clarification of policy criteria according to recommendations made in CPRG 2018/19 Meeting 1.
1819.2.00	01/10/2018	IFR Coordinator	Smoking and BMI references updated following September CPRG and PALS info updated

1819.2.01	14/02/2019	CPD Manager	Clarification within policy of section 6 and 7. Insertion of locally agreed need to manage in primary care through lifestyle advice in first instance. Punctuation of criteria statement

THIS IS A CRITERIA BASED ACCESS POLICY

TREATMENT MAY BE PROVIDED WHERE PATIENTS MEET THE CRITERIA BELOW

THIS POLICY RELATES TO ADULT PATIENTS – OVER 18 YEARS

Gallbladder Removal in Adults Patients – Over 18 Years Policy

General Principles

Treatment should only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB Exceptional Funding Request Panel.

1. Clinicians should assess the patients against the criteria within this policy prior to referring patients seeking treatment. Referring patients to secondary care that do not meet these criteria not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment.
2. Patients will only meet the criteria within this policy where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment and the EFR team should be approached for advice.
3. On limited occasions, the ICB may approve funding for a further assessment in secondary care only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meets the criteria to access treatment in this policy.
4. Where funding approval is given by the Exceptional Funding Request Panel, it will be available for a specified period of time, normally one year.
5. Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be encouraged to lose weight further prior to seeking surgery. https://www.sciencedirect.com/science/article/pii/S1198743X15007193 (Thelwall, 2015).
6. Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing (ASH, 2016)
7. In applying this policy, all clinicians and those involved in making decisions affecting

patient care will pay due regard to the need to eliminate unlawful discrimination, harassment, victimisation, etc., and will advance equality of opportunity and foster good relations between people who share a protected characteristic and those who do not. In particular, due regard will be paid in relation to the following characteristics protected by the Equality Act 2010: age, disability, sex, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief and sexual orientation.

Background/Purpose and Scope

The gallbladder is a small, pouch-like organ situated underneath the liver. The main purpose of the gallbladder is to store and concentrate bile. Bile is a liquid produced by the liver which helps digest fats. It is passed from the liver through a series of channels, known as bile ducts, into the gallbladder.

The bile is stored in the gallbladder and over time it becomes more concentrated, which makes it better at digesting fats. The gallbladder is able to release bile into the digestive system when it is needed. A gallstone (cholelithiasis) is a solid deposit that forms within the gallbladder. One or more gallstones may form.

Causes of Gallstones

It is thought that gallstones develop because of an imbalance in the chemical make-up of bile inside the gallbladder. In most cases the level of cholesterol in bile becomes too high and the excess cholesterol forms into stones. Gallstone disease is a general term that describes the presence of one or more stones in the gallbladder or other parts of the biliary tree, and the symptoms and complications they may cause.

Gallstones are very common. It is estimated that more than 1 in every 10 adults in the UK has gallstones, although only a minority of people will develop symptoms. Most people with gallstone disease are asymptomatic and will remain asymptomatic (i.e. experience no pain/ discomfort from their gallstones). However, each year about 2- 4% of people with previously asymptomatic gallstones will develop symptoms or complications.

Symptoms of Gallstones

Most cases of gallstones don't cause any symptoms. But if a gallstone blocks one of the bile ducts, it can cause sudden, severe abdominal pain, known as biliary colic.

Other symptoms may develop if the blockage is more severe or develops in another part of the digestive system.

Abdominal pain (biliary colic)

Gallstones can cause sudden, severe abdominal pain that usually lasts one to five hours (although it can sometimes last just a few minutes).

The pain can be felt:

- in the centre of your abdomen (tummy)
- just under the ribs on your right-hand side – it may spread from here to your side or shoulder blade

The pain is constant and isn't relieved when you go to the toilet, pass wind or are sick. It's sometimes triggered by eating fatty foods, but may occur at any time of day and it may wake you up during the night.

Biliary colic doesn't happen often. After an episode of pain, it may be several weeks or months before you experience another episode.

Some people also have periods where they sweat excessively and feel sick or vomit. When gallstones cause episodes of biliary colic, it is known as "uncomplicated gallstone disease".

Other symptoms

In a small number of people, gallstones can cause more serious problems if they obstruct the flow of bile for longer periods or move into other organs (such as the pancreas or small bowel).

If this happens, you may develop:

- a high temperature of 38C (100.4F) or above
- more persistent pain
- a rapid heartbeat
- yellowing of the skin and whites of the eyes (jaundice)
- itchy skin
- diarrhoea
- chills or shivering attacks
- confusion
- a loss of appetite

You are more at risk of developing gallstones if you are:

- **overweight or obese** – *as well as actively losing weight.*
- **female** – women are two to three times more likely to be affected by gallstone disease than men.
- **40 or over** – most cases of gallstone disease first develop in people aged 40 or older and the risk increases as you get older.
- **a mother** – women who have had children have an increased risk of gallstone disease, which may be because the hormonal changes that occur during pregnancy increase cholesterol levels.

Treating Gallstones

Treatment is only usually necessary if gallstones are causing symptoms, such as abdominal pain.

In these cases, keyhole surgery to remove the gallbladder may be recommended. This procedure, known as a **laparoscopic cholecystectomy**, is relatively simple to perform and has a low risk of complications.

Prophylactic cholecystectomy is the removal of the gallbladder in order to remove the risk of future disease. Funding is only approved on the basis of clinical information being supplied to confirm the need for this preventative treatment.

What are the complications?

In some people, gallstones cause one or more complications. These include:

- **Biliary colic -** this is pain caused by the gallbladder, cystic duct, or common bile duct contracting around a gallstone. It is, by far, the most common complication of gallstones. Repeated bouts of biliary colic may develop.
- **Acute cholecystitis -** this is inflammation or infection of the gallbladder and is the second most common complication of gallstones. Acute infective cholecystitis may progress to more severe infection and empyema of the gallbladder which may then progress to perforation and fistula formation.
- **Obstructive jaundice -** a partially or completely blocked common bile duct causes an accumulation of bile pigments in the bloodstream to cause an obstructed pattern of jaundice. The obstruction is caused most commonly by a stone that has passed from the gallbladder into the bile duct. Rarely, it is due to compression of the common bile duct or the common hepatic duct by a stone in the neck of the gallbladder or cystic duct (Mirizzi's syndrome).

All other complications are uncommon or rare, and include:

- **Cholangitis (also called ascending cholangitis)** is inflammation or infection of the common bile duct. A gallstone in the common bile duct can cause stasis of bile leading to an increase in microbial activity.
- **Gallstone pancreatitis** is a stone that has migrated along the common bile duct may become stuck in the biliopancreatic duct which may trigger a pancreatitis.
- **A fistula** may form, rarely, between an inflamed gallbladder and the small bowel. A migrating stone may then cause a bowel obstruction. If this occurs in the duodenum it is called Bouveret's syndrome. If it occurs in the ileum it is known as gallstone ileus

(a misnomer, as the small bowel obstruction is mechanical and not an ileus).

- **Xanthogranulomatous cholecystitis** is a rare destructive inflammatory process that damages the gallbladder.

- **Biliary peritonitis** may develop if bile leaks into the peritoneal cavity due to perforation of the gallbladder or biliary tree as a result of severe gallbladder infection or severe bile duct obstruction.
- **Gallbladder mucocele** is a distended gallbladder that is filled with non-inflammatory mucoid fluid. It is typically caused by an impacted gallstone in the cystic duct.
- **Gallbladder cancer** may be a rare complication, but the association between gallstones and gallbladder cancer is tenuous.

(Sanders & Kingsnorth, 2007), (Gurusamy & Davidson, 2014)

You can lead a perfectly normal life without a gallbladder. The organ can be useful but it is not essential. Your liver will still produce bile to digest food, but the bile will just drip continuously into the small intestine, rather than build up in the gallbladder.

(NHS Choices, 2015) (NICE, 2014)

POLICY CRITERIA – COMMISSIONED

CRITERIA BASED ACCESS

SYMPTOMATIC GALLSTONES ONLY

Cholecystectomy is the surgical removal of the gallbladder.

Cholecystectomy will be funded for patients with symptomatic gallstones where there is evidence of symptoms associated with gallstones. ***This must be clearly documented within the patient records of two* or more episodes resulting in pain/nausea linked with any of the following:***

1. Calculus of gallbladder with ***acute*** cholecystitis

OR

2. Calculus of gallbladder with ***other*** cholecystitis

OR

3. Calculus of bile duct with cholangitis (infection of the bile duct)

OR

4. Calculus of bile duct with cholecystitis

OR

5. Calculus of gallbladder with impacted gallstone or recurrent Biliary Colic

In addition to the above a Cholecystectomy will be funded for patients in the following instances :

6. Emergency presentation of acalculous cholecystitis where surgery is appropriate

OR

7. After pancreatitis (if appropriate)

Management of Symptomatic Gallstones

* Locally patients with severe symptoms attend HOT clinics and a resolution is normally achieved through this route.

Therefore it has been agreed that for those patients who present in primary care with symptoms of nausea / pain potentially demonstrating symptomatic gallstones in the first instance lifestyle and management advice given.

Referrals should only be made in line with this policy following a second episode of pain and / or nausea.

Management of Asymptomatic Gallstones

NICE recommends that no treatment is required for the management of Asymptomatic Gallstones when found in a normal gallbladder, and with a normal biliary tree, (NICE, 2014)

A watch-and-wait approach is recommended for asymptomatic gallstones, with referral for active treatment only recommended if the stones begin to cause symptoms.

This policy does not support the funding of removal of Asymptomatic Gallstones outside of the criteria listed below and this treatment is not routinely commissioned.

POLICY CRITERIA – COMMISSIONED CRITERIA BASED ACCESS
ASYMPTOMATIC GALLSTONES ONLY **Cholecystectomy is the surgical removal of the gallbladder.** **Prophylactic cholecystectomy is not indicated in most patients with asymptomatic gallstones.** **The removal of the gallbladder for asymptomatic / silent gallstones will only be considered if the patient has one or more of the following *and this is clearly documented in the patient records:*** **1.** Gallbladder polyp(s) as detailed in the ESGAR management pathway below. **OR** **2.** Sickle Cell disease or other chronic haemolytic diseases. **OR** **3.** An increased risk of developing complications (with non-functioning gallbladder, choledocholithiasis and obstructive jaundice).
Note: Patients with Asymptomatic Gallstones under the care of a Cancer MDT are outside of the scope of this policy

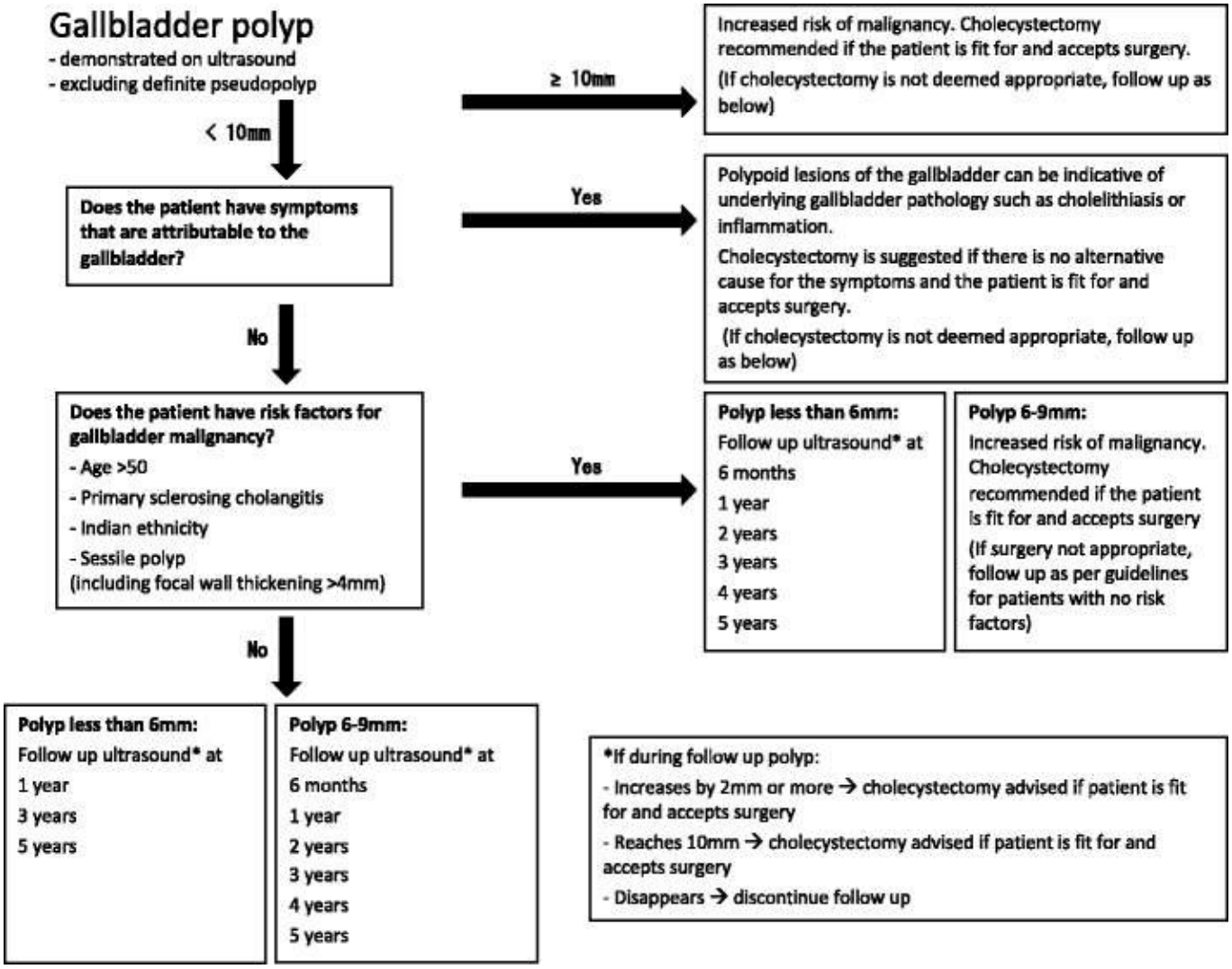
Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the ICB's Individual Funding Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on **BNSSG.customerservice@nhs.net** .

ESGAR Polyp Management Pathway

Joint guidelines between the European Society of Gastrointestinal and Abdominal Radiology (ESGAR), European Association for Endoscopic Surgery and other Interventional Techniques (EAES), International Society of Digestive Surgery – European Federation (EFISDS) and European Society of Gastrointestinal Endoscopy (ESGE)



(Wiles, Thoeni, Barbu, & al., 2017)

Connected Policies

- Spyglass

This policy has been developed with the aid of the following references:

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Gurusamy, K. S., & Davidson, B. R. (2014). Gallstones. *BMJ*, 348:g2669.

NHS Choices. (2015, November 6th). *Gallstones* . Retrieved from NHS Choices: http://www.nhs.uk/conditions/Gallstones/Pages/Introduction.aspx

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NICE. (n.d.). *https://cks.nice.org.uk*. Retrieved 08 15, 2017, from https://cks.nice.org.uk/gallstones#!scenario: https://cks.nice.org.uk

Sanders, G., & Kingsnorth, A. N. (2007). Gallstones. *BMJ*, 295-299.

Thelwall, S. P. (2015). Impact of obesity on the risk of wound infection following surgery: results from a nationwide prospective multicentre cohort study in England. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases,* , vol. 21, no. 11, p. 1008.e1.

Wiles, R., Thoeni, R., Barbu, S., & al., e. (2017). Management and follow-up of gallbladder polyps. 27: 3856.

OPCS Procedure codes – For completion at a later date
