LAPAROSCOPIC CHOLECYSTECTOMY FOR ASYMPTOMATIC GALL STONES
CRITERIA BASED ACCESS (CBA) POLICY

Version:	2223.v2b
Recommendation by:	NHS Somerset ICB Clinical Commissioning Policy Forum (CCPF)
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Target audience:	**NHS Somerset ICB**: • NHS Providers • GP Practices • Contracts Team **Medical Directors:** • Somerset Foundation Trust • Yeovil District Hospital NHS FT • Royal United Hospitals Bath NHS FT
Application Form	EBI Generic application form if appropriate to apply

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Commented [MK(SC1]: Background might be removed -when removed updated section numbers etc.

VERSION CONTROL

Document Status:	Current policy
Version:	2223.v2a

DOCUMENT CHANGE HISTORY		
Version	**Date**	**Comments**
1617.v1a	July 2017	Change from the CSU template to the SCCG template
1617.vb	June 2020	Update template, rebranding from IFR to EBI, 3 year review no clinical amendments
2021.v2	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.v2a	January 2023	3 yr review, no clinical changes. Wording change on 4.6

Equality Impact Assessment (EIA)	April 2018
Quality Impact Assessment QIA	March 2018
Sponsoring Director:	Bernie Marden
Document Reference:	2223.v2b

1 GENERAL PRINCIPLES (CBA)

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1.1 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's Evidence Based Interventions Service (EBI) by submission of an EBI application form

1.2 Clinicians should assess their patients against the criteria within this policy prior to a referral and/or treatment

1.3 Treatment should only be undertaken where the criteria have been met and 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

1.4 Referring patients to secondary / community care without them meeting the criteria or funding approval not secured 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

1.5 On limited occasions, the ICB may approve funding for an assessment 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 meet the criteria to access treatment in this policy

1.6 Patients should be advised being referred does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment

1.7 The policy does not apply to patients with suspected malignancy who should continue to be referred under 2 week wait pathway rules for assessment and testing as appropriate

1.8 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)

1.9 Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing

2 POLICY CRITERIA

2.1 The removal of the gallbladder for asymptomatic gallstones is not routinely funded by the Commissioner

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

2.3 The removal of the gallbladder for asymptomatic (or symptoms subsequently deemed related to) gallstones is commissioned for patient fulfilling any one of the following criteria;

Treatment for patients fulling any one of the criteria should be in line with NICE CG188 and the associated quality standard

a. Patients with diabetes mellitus/transplant recipient patients/patients with cirrhosis who have been managed conservatively and subsequently develop symptoms

b. Where there is clear evidence of patients being at risk of gallbladder carcinoma

c. Where there is clear evidence of patients being at risk of gallbladder complications

d. Confirmed episode of gall stone induced pancreatitis

e. Confirmed episode of cholecystitis

f. Episode of obstructive jaundice caused by biliary calculi

3 BACKGROUND

3.1 Gallstones are small stones, usually made of cholesterol, that form in the gallbladder

3.2 About 15% of adults are thought to have gallstone disease. Of these, around 80% have asymptomatic gallbladder stones (stones that are only found in the gallbladder and that cause no symptoms). They are often found by investigations for other conditions, and adults with asymptomatic gallbladder stones may never develop symptoms or complications

3.3 Around 20% of people with the condition have symptomatic gallstone disease. The symptoms of gallstone disease range from mild, non-specific symptoms that can be difficult to diagnose, to severe pain and/or complications that are often easily recognised as gallstone disease by healthcare professionals

3.4 Adults with mild, non-specific symptoms of gallstone disease may think their symptoms are caused by other conditions, or they may be misdiagnosed and have unnecessary investigations and treatment. This can have a negative effect on their quality of life and can be an unnecessary cost for the NHS. There is a need to identify whether there are any specific signs, symptoms or risk factors for gallstone disease and the best method of diagnosing it

4 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

4.1 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

4.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required

4.3 Applications cannot be considered from patients personally

4.4 Only electronically completed EBI applications will be accepted to the EBI Service

4.5 It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the EBI service. This will reassure the service that the patient has a reasonable expectation of the outcome of the application and its context

4.6 EBI applications are reviewed and considered against clinical exceptionality

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB website and input into the 'Search this website' box clinical exceptionality. Click on the link to access the full NHS description of clinical exceptionality

Social, Emotional and Environmental factors *i.e., income, housing, environmental pollution, access to services, family, friends, ethnicity, life experiences etc.* CANNOT be considered with an application

4.7 Where appropriate photographic supporting evidence can be forwarded with the application form

4.8 An application put forward for consideration must demonstrated some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:

- Significantly different to the general population of patients with the condition in question

- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

5 ACCESS TO POLICY

5.1 If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067

5.2 **Or write to us**: NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

6 REFERENCES

The following sources have been considered when drafting this policy:

6.1 NICE CG188 available at: https://www.nice.org.uk/guidance/cg188/

6.2 Afdhal N. Approach to the management of gallstones. *UpToDate* July 2022. Available at: https://www.uptodate.com/contents/approach-to-the-management-of-gallstones?search=incidental%20gallstones&source=search_result&selectedTitle=1~25&usage_type=default&display_rank=1

6.3 Meshikhes A. Asymptomatic Gallstones in the Laparoscopic Era. J.R. College of Surgery, Edinb. December 2002 47(6):742-8. Available at: Asymptomatic gallstones in the laparoscopic era - PubMed (nih.gov)

6.4 Gurusamy KS, Samraj K. Cholecystectomy for patients with silent gallstones. *Cochrane Database of Systematic Reviews* 2007, Issue 1. Art. No.: CD006230. DOI: 10.1002/14651858.CD006230.pub2.

6.5 McAlister V, Davenport E, Renouf E. Cholecystectomy deferral in patients with endoscopic sphincterotomy. *Cochrane Database of Systematic Reviews* 2007, Issue 4. Art. No.: CD006233. DOI: 10.1002/14651858.CD006233.pub2