

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

Version:	2526.v2d
Recommendation by:	NHS Somerset ICB Clinical Commissioning Policy Forum (CCPF)
Date Ratified:	October 2025
Name of Originator/Author:	EBI Service
Approved by Responsible Committee/Individual:	NHS Somerset Management Board
Publication/issue date:	November 2025
Review date:	Earliest of either NICE publication or 3 years from issue
Target audience:	<p>NHS Somerset ICB:</p> <ul style="list-style-type: none"> • NHS Providers • GP Practices • Contracts Team <p>Medical Directors:</p> <ul style="list-style-type: none"> • Somerset NHS Foundation Trust • Royal United Hospitals Bath NHS FT
Application Form	EBI Generic application form if appropriate to apply

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VERSION CONTROL

Document Status:	Current policy
Version:	2526.v2d

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-year review, no clinical changes. Wording change on 4.6
2223.v2b	July 2024	Logo change with amendment to website link and clinical exceptionality wording on 4.6
2425.v2c	October 2025	3-year review, no clinical amendments. Amendment to wording under general principles and EBI pathway

Equality Impact Assessment (EIA)	April 2018
Quality Impact Assessment QIA	March 2018
Sponsoring Director:	Bernie Marden
Document Reference:	2526.v2d

1 GENERAL PRINCIPLES (CBA)

- 1.1 Treatment should only be given in line with these general principles.
- 1.2 Clinicians should assess their patients against the criteria within this policy AND ENSURE that compliance to the policy criteria is met by the patient PRIOR TO a referral to treatment or surgery
- 1.3 Treatment should ONLY be undertaken where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment
- 1.4 The ICB may approve funding for an ASSESSMENT ONLY to enable the Clinician to obtain further clinical evidence to help determine compliance to policy criteria by the patient.
- In such cases, patients should be made aware that an assessment DOES NOT mean that they will automatically receive the treatment or surgery. The patient should be advised that, to effectively manage patient safety and ensure efficacy of the treatment/ surgery for the patient, they will only receive treatment or surgery if they meet policy criteria
- 1.5 Patients MUST CONSENT to receiving treatment/ surgery prior to treatment being undertaken
- 1.6 This policy does not apply to patients with suspected malignancy who should continue to be referred under the NHS '2 week wait pathway' rules for assessment and testing as appropriate
- 1.7 Patients with an elevated BMI of 30 or more MAY experience more post-surgical complications including post-surgical wound infection and should be encouraged to lose weight further prior to seeking surgery
- <https://www.sciencedirect.com/science/article/pii/S1198743X15007193>
(Thelwall, 2015)
- 1.8 Patients who are smokers should be referred to smoking cessation services to reduce the risk of surgery and improve healing
- 1.9 Where patients are unable to meet the specific treatment criteria set out in this policy, funding approval MAY be sought by submission of a Generic EBI application form to the Evidence Based Interventions (EBI) team on grounds of 'clinical exceptionality'

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 patient's fulfilling 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
- 2.4 Patients who are not eligible for treatment under this policy, please refer to section 4 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS on how to apply for funding with evidence of clinical exceptionality

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 surgery under this policy may be considered for surgery on an individual basis where the 'CLINICIAN BEST PLACED' believes exceptional circumstances exist that warrant deviation from the rule of this policy

'THE CLINICIAN BEST PLACED' is deemed to be the GP or Consultant undertaking a medical assessment and/or a diagnostic test/s to determine the health condition of the patient

- 4.2 Completion of a **Generic EBI Funding Application Form** must be sent to the EBI team by the 'clinician best placed' on behalf of the patient

Note. applications CANNOT be considered from patients personally

- 4.3 Only electronically completed EBI applications emailed to the EBI Team will be accepted

- 4.4 It is expected that clinicians will have ensured that the patient, on behalf of whom they are forwarding the funding application, has given their consent to the application and are made aware of the due process for receiving a decision on the application within the stated timescale

- 4.5 Generic EBI Funding Applications are considered against '**clinical exceptionality**'. To eliminate discrimination for patients, social, environmental, workplace, and non-clinical personal factors CANNOT be taken into consideration.

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB EBI webpage [Evidence Based Interventions - NHS Somerset ICB](#) and click on the section titled **Generic EBI Pathway**

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

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&u_sage_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