NHS
Coventry and Rugby
Clinical Commissioning Group

Gallstone Surgery Policy

VERSION CONTROL

Version:	4.0
Ratified by:	Governing Body Meetings in Common
Date ratified:	26 September 2019
Name of originator/author:	Joint CCG Clinical Commissioning Policy Development Group
Name of responsible committees:	Clinical Quality and Governance
Date issued:	September 2019
Review date:	September 2022

VERSION HISTORY

Date	Version	Comment / Update
11/11/15	3.0	Approved at Governing Body meeting
26/09/19	4.0	Approved at Governing Body Meetings in Common. Review of evidence - No changes from version 3.0.

Commissioning Policy: Coventry and Rugby CCG (CRCCG)

This document refers specifically to Gallstone Surgery.

Treatment	Gallstone Surgery
Indication	Gallstones
	There is an expectation that gallstones would be managed in line with NICE clinical guidance CG188 which reads as follows: 1.2 Managing gallbladder stones 1.2.1 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. 1.2.2 Offer laparoscopic cholecystectomy to people diagnosed with symptomatic gallbladder stones. **Prior approval from the Clinical Commissioning Group will be required before any treatment proceeds in secondary care.**
Quality and Equality Impact Assessment	See attached document.

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Quality and Equality Impact Assessment

Scheme Title:	Gallstone Surgery Policy		
Project Lead:	Clive Campton, IFR Manager Kate Cogman, Contracts Manager	**Senior Responsible Officer:**	Steve Allen, Clinical Director
		Quality Sign Off:	Mary Mansfield, Deputy Director of Nursing
Intended impact of scheme:	The Gallstone Surgery policy supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within CCG budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.		
How will it be achieved:	The Governing Body adopts the policy.		

Name of person completing assessment:	**Clive Campton** **Kate Cogman**
Position:	**IFR Manager** **Contracts Manager**
Date of Assessment:	**12/06/19**

Quality Review by:	**Mary Mansfield**
Position:	**Deputy Director Nursing and Quality**
Date of Review:	**17 July 2019**

Stage 1a: High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		**OUTCOME ASSESSMENT** (Please tick one)			**Evidence/Comments for answers**	**Risk rating** (For negative outcomes)			**Mitigating actions**
		Positive	**Negative**	**Neutral**		**Risk impact** (I)	**Risk likelihood** (L)	**Risk Score** (IxL)	
Duty of Quality Could the scheme impact positively or negatively on any of the following:	Effectiveness – clinical outcome	✓			Policy based on NICE guidance				
	Patient experience			✓	Adopting the policy will not have an impact.				
	Patient safety			✓	Adopting the policy will not have an impact.				
	Parity of esteem			✓	Adopting the policy will not have an impact.				
	Safeguarding children or adults			✓	Adopting the policy will not have an impact.				
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	✓			Policy based on NICE guidance, aimed at preventing ill health.				
	Ensuring people have a positive experience of care			✓	Adopting the policy will not have an impact.				
	Preventing people from dying prematurely			✓	Adopting the policy will not have an impact.				
	Helping people recover from episodes of ill health or following injury			✓	Adopting the policy will not have an impact.				
	Treating and caring for people in a safe environment and protecting them from avoidable harm			✓	Adopting the policy will not have an impact.				

Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors			✓	Adopting the policy will not have an impact.				
	Access to the highest quality urgent and emergency care			✓	Adopting the policy will not have an impact.				
	Convenient access for everyone			✓	Adopting the policy will not have an impact.				
	Ensuring that citizens are fully included in all aspects of service design and change			✓	Adopting the policy will not have an impact.				
	Patient Choice			✓	Adopting the policy will not have an impact.				
	Patients are fully empowered in their own care			✓	Adopting the policy will not have an impact.				
	Wider primary care, provided at scale			✓	Adopting the policy will not have an impact.				
Access Could the proposal impact positively or negatively on any of the following:	Patient choice			✓	Adopting the policy will not have an impact.				
	Access			✓	Adopting the policy will not have an impact.				
	Integration			✓	Adopting the policy will not have an impact.				
Compliance with NHS Constitution	Quality of care and environment	✓			Policy based on NICE guidance, aiming to improve quality of care and services				
	Nationally approved treatment/drugs	✓			Policy adopts NICE guidance.				
	Respect, consent and confidentiality			✓	Adopting the policy will not have an impact.				
	Informed choice and involvement			✓	Adopting the policy will not have an impact.				
	Complain and redress			✓	Adopting the policy will not have an impact.				

*Risk score definitions are provided in the next section.

Risk rating score definition

Likelihood	Impact
1 – Rare	1 – Negligible
2 – Unlikely	2 – Minor
3 – Moderate	3 – Moderate
4 – Likely	4 – Major
5 – Almost certain	5 – Catastrophic

	Likelihood				
Consequence	Rare (1)	Unlikely (2)	Possible (3)	Likely (4)	Almost Certain (5)
Catastrophic (5)	5	10	15	20	25
Major (4)	4	8	12	16	20
Moderate (3)	3	6	9	12	15
Minor (2)	2	4	6	8	10
Negligible (1)	X-1	2	3	4	5

How will a successful implementation of quality indicators be measured?

Quality Outcome	Measured By
Positive Health Outcome	Triangulation of Incidents Complaint and Patient Experience trends

Stage 1b: Equality Questions

The Public Sector Equality Duty requires us to **eliminate** discrimination, **advance** equality of opportunity and **foster** good relations with protected groups. Consider how this policy / service will achieve these aims.

Other partners/stakeholders involved in scheme: N/A

Who will be affected by this piece of work? CCG registered patients

PROTECTED GROUP	Is there likely to be a differential impact? (Please tick one)			Evidence/Comments for answers. Where available please share any baseline data and research on the population that this piece of work will affect. Include any consultations with service users that have been carried out.
	YES	NO	UNKNOWN	
Gender	✓			Evidence shows a higher prevalence of gallstones observed in women in all age groups. The difference between women and men is particularly striking in young adults. The GREPCO study found a female- to-male ratio of 2.9 between the ages of 30 to 39 years; the ratio narrowed to 1.6 between the ages of 40 to 49 years and 1.2 between the ages of 50 to 59 years. The higher rates in young women are almost certainly a result of pregnancy and sex steroids.
Race	✓			As a general rule, there appears to be higher rates of cholelithiasis in western Caucasian, Hispanic, and Native American populations and lower rates in eastern European, African American, and Japanese populations.
Disability (including mental impairment, learning difficulty)		✓		Adopting the policy will not have an impact.
Religion/belief		✓		Adopting the policy will not have an impact.
Sexual orientation		✓		Adopting the policy will not have an impact.
Age	✓			Age is a major risk factor for the gallstones. Gallstones are exceedingly rare in children except in the presence of haemolytic states; in addition, less than 5 percent of all cholecystectomies are performed in children. Age 40 appears to represent the cut-off between relatively low and high rates of cholecystectomies. This observation was validated in the Sirmione study in which the incidence between the ages of 40 and 69 years was four times higher than that in younger subjects. Among the 135 patients with gallstones, only one was between the ages of 18 and 21 years.

Social deprivation		✓		Adopting the policy will not have an impact.
Carers		✓		Adopting the policy will not have an impact.
Human rights		✓		Adopting the policy will not have an impact.
Pregnancy and Maternity	✓			Pregnancy is a major risk factor for the development of cholesterol gallstones. The risk is related to both the frequency and number of pregnancies. In one report, for example, the prevalence of gallstones increased from 1.3 percent in nulliparous females to 12.2 percent in multiparous females. Another study recruited 272 women in the first trimester of pregnancy. The incidence of new biliary sludge and gallstones was 31 and 2 percent, respectively.

References

- Br J Surg. 2004 Jun;91(6):734-8. Development of symptoms and complications in individuals with asymptomatic gallstones. Halldestam I1, Enell EL,
  Kullman E, Borch K.
- UpToDate (2014) Epidemiology of and risk factors for gallstones [online] http://www.uptodate.com/contents/epidemiology-of-and-risk-factors- for-gallstones?source=search_result&search=gallstones&selectedTitle=4~150 (accessed 06/08/15)
- https://www.bmj.com/bmj/section-pdf/755948?path=/bmj/348/7955/Clinical_Review.full.pdf
- https://www.nhs.uk/conditions/gallstones/ (accessed 25.03.19)
- https://www.nice.org.uk/guidance/cg188/documents/cholelithiasis-and-cholecystitis-final-scope2
- https://www.nice.org.uk/guidance/cg188/evidence/full-guideline-pdf-193302253

Stage 1c: Post Implementation Review

Use the template below to record outcomes of reviews – if more than one is required cut and paste the box below:

Quality Impact	**Has there been a differential impact?** (Please tick one)			**Evidence/Comments for answers**	**Mitigations**
	YES	**NO**	**UNKNOWN**		