

Clinical Commissioning Policy

CMICB_Clin092

Subacromial shoulder pain, arthroscopic shoulder decompression surgery

(Based on Evidence Based Intervention (EBI) Programme Best Practice Guidance)

Category 2 Intervention - Only routinely commissioned when specific criteria are met

Contents

1.	Policy statement	2
2.	Exclusions	2
3.	Core Eligibility Criteria	3
4.	Rationale behind the policy statement	3
5.	Summary of evidence review and references	3
6.	Advice and Guidance	7
7.	Monitoring and Review	8
8.	Quality and Equality Analysis	9
9.	Clinical Coding	9
Document Control10		

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This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

- 1.1 Where MCAS services are in place the patient needs to be seen in a Musculoskeletal Clinical Assessment (MCAS) service before referral to a consultant.
- 1.2 Arthroscopic subacromial decompression surgery for pure subacromial pain is routinely commissioned if **all** the criteria below are satisfied:
 - The pain has been present for at least 12 months.

AND

- The following "red flag" warnings have all been excluded:
 - Acute, painful, red warm joint (suspected infection).
 - Trauma (with loss of rotation and abnormal shape, unreduced dislocation).
 - Shoulder mass/swelling (suspected malignancy).
 - Sudden inability to actively raise the arm, with or without trauma (acute cuff tear).
 - New symptoms of inflammation in several joints (suspected systemic inflammatory joint disease).

AND

• There are no signs of calcific tendinopathy/tendinitis.

AND

• There is no history of rotator cuff tear or acromioclavicular joint pain.

AND

• Suitable shoulder specific exercises have been performed for at least 3 months and up to 2 subacromial corticosteroid injections have been administered.

AND

• Despite (3.5) above, the patient's pain and loss of function persist.

AND

• The patient is considered fit for surgery.

AND

• After a discussion between the surgeon and patient, a joint decision is taken to proceed with surgery.

2. Exclusions

- 2.1 The conditions described as "red flag" warnings (paragraph 3.2) should be considered and are excluded from this policy.
- 2.2 Shoulder arthroscopy for indications other than pure subacromial shoulder pain are not within the scope of this policy.

3. Core Eligibility Criteria

- 3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.
- 3.2 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 expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the <u>NHS England gender</u> <u>services programme</u> - <u>https://www.england.nhs.uk/commissioning/spec-services/npccrg/gender-dysphoria-clinical-programme/</u>

4. Rationale behind the policy statement

- 4.1 The Evidence Based Interventions (EBI) programme <u>https://ebi.aomrc.org.uk/resources/</u> recommends arthroscopic subacromial decompression for pure subacromial shoulder impingement only in appropriate cases.
- 4.2 This policy recommendation takes the EBI recommendation into account supplemented by other published evidence and expert opinion.

5. Summary of evidence review and references

5.1 *Rotator cuff disease* is an umbrella term affecting the shoulder which describes various diagnoses such as rotator cuff tendinopathy, shoulder impingement syndrome, partial or complete rotator cuff tears, calcific tendinitis and subacromial bursitis. The mechanisms of these conditions may be of an inflammatory or degenerative nature or due to acute injury. In general, however, patients will present with shoulder pain which is aggravated by overhead movement and is often worse at night when lying on the affected side which leads to disrupted sleep.¹

Cheshire and Merseyside Integrated Care Board

- 5.2 Shoulder pain is regarded as the 3rd most prevalent type of muscular skeletal disorder and affects one in three individuals. ² Subacromial impingement syndrome accounts for nearly two thirds of shoulder disorders and is associated with pain and significant impairment in function and reduction in health-related quality-of-life. First-line treatment is usually conservative and arthroscopic subacromial decompression can be considered for patients who fail to respond to non-surgical management. ³ Conservative measures include NSAIDs, corticosteroid injections into the joint and exercises which are intended to improve muscle function as well as the range of motion by restoring shoulder mobility, proprioception, and stability.²
- 5.3 Subacromial decompression surgery or acromioplasty involves excision of the bony spur on the antero-inferior surface of the acromion, excision of the bursal tissue and release of the ligaments. The objective of the procedure is to increase the volume of the subacromial space which reduces the mechanical attrition and irritation of the rotator cuff tendons.⁴
- 5.4 The evidence of effectiveness on subacromial decompression surgery is a controversial area. In 2019, Vandvik published a "rapid recommendation" in the BMJ and recommended that subacromial decompression surgery should not be offered to patients with subacromial pain syndrome. ⁵ The rapid recommendation was based on a substantive systematic review and meta-analysis by Lähdeoja.⁶ In turn, Lähdeoja relied on 2 randomised controlled trials (RCTs) from Beard (based in the UK)⁷ and Paavola (based in Finland)⁸.
- 5.5 The substantive systematic review by Lähdeoja ⁶ had set out to determine the benefits and harms of subacromial decompression in adults with subacromial pain syndrome lasting greater than 3 months. The review didn't specify strict diagnostic criteria (because the diagnosis is usually a clinical one) and there was no requirement for imaging. Trials were excluded for patients with calcific tendinitis, full-thickness rotator cuff tears and secondary shoulder pain (e.g. due to trauma or thrower's shoulder). It is reasonable to infer that some patients with smaller rotator cuff tears could have been included. In addition, the intention to treat (ITT) populations for Beard and Paavola were n = 59 and n = 106 respectively. Because of the low numbers, the relative lack of UK participants and inclusion of patients with small rotator cuff tears, the relevance of these results to a UK population with pure subacromial pain is questionable.
- 5.6 At the time of the Lähdeoja review, a BMJ editorial ⁹ commented on its findings. Although the editorial acknowledged that the benefit of arthroscopic decompression had divided opinion among health professionals for years, the article went on to point out the deficiencies in Lähdeoja's work which included inconsistent terminology, short-term follow-up periods (around 2 years when longer term studies have suggested benefit after 10 years), concerns about small sample sizes, group crossover, low numbers of procedures per surgeon and the failure to standardise surgical technique. The editorial concluded that healthcare professionals should be cautious in their approach to arthroscopic subacromial decompression, but the current evidence base is not strong enough to condemn it.
- 5.7 Other articles published at this time include a small study which found that surgery was beneficial in 28 patients in Malaysia¹⁰ and an overview of 15 systematic reviews which found no differences in clinical outcomes between exercise therapy and surgery.² However, disparities in the methodological quality of the latter were noted which could affect the quality of the results. Overall, shoulder specific exercises should be considered the first line of conservative treatment to improve clinical outcomes.

National guidelines

- 5.8 Early guidance was published (2014) in the form of a Commissioning Guide for subacromial shoulder pain by collaboration between the British Orthopaedic Association (BOA), the Royal College of Surgeons (RCS) and the British Elbow and Shoulder Society (BESS).¹¹ This guide is still current and in primary care, patients should initially be screened for the following "red flag" signs/symptoms:
 - Acute, painful, red warm joint (suspected infection).
 - *Trauma* (with loss of rotation and abnormal shape, unreduced dislocation).
 - Shoulder mass/swelling (suspected malignancy).
 - Sudden *inability to actively raise the arm*, with or without trauma (acute cuff tear).
 - New symptoms of *inflammation in several joints* (suspected systemic inflammatory joint disease).
- 5.9 Subsequent management within primary care then involves patient education, rest, NSAIDs, physiotherapy and a single injection of corticosteroid into the subacromial space. Caution is advised for repeat injections owing to possible tendon damage. Referral to secondary care is considered appropriate for persistent pain which hasn't responded to at least 6 weeks of nonsurgical treatments.
- 5.10 In secondary care, surgery may be appropriate for persistent or significant pain and loss of function despite appropriate nonoperative treatment. The indications for arthroscopic subacromial decompression (acromioplasty) may be considered for:
 - Failure of appropriate conservative management.
 - Pain in the absence of a rotator cuff tear.
 - Pain with an irreparable rotator cuff tear or
 - Pain with a cuff tear which the patient chooses not to have repaired.
- 5.11 In addition, the BESS/BOA pathway ⁴ (which complements the commissioning guide) specifies that although acute calcific tendinopathy isn't a red flag, this is extremely painful and often mimics malignant pain and thus usually requires an early secondary care referral.
- 5.12 NHS England's Evidence Based Intervention (EBI) programme ¹² permits arthroscopic subacromial decompression in patients with "pure subacromial" pain who have persistent or progressive symptoms in spite of adequate nonoperative treatment. EBI defines this as pain not caused by associated diagnoses such as rotator cuff tears, acromio-clavicular joint pain, or calcific tendinopathy. Whilst EBI acknowledges the controversy behind this intervention, the programme statement urges surgeon and patient to discuss the latest evidence and reach a shared decision before deciding to proceed with surgery. EBI did not consider the rapid review ⁵ or its underpinning systematic review ⁶ previously discussed above.
- 5.13 In conclusion, it is evident from this literature review that the topic of surgery for subacromial pain is surrounded by controversy. On one hand, EBI recommends arthroscopic decompression for pure subacromial pain, whereas Vandvik's ⁵ *et al* rapid review (whose validity and generalisability are in question) holds the opposite view. Current practice dictates that this procedure is appropriate in some cases, and this is supported by the BOA/BESS national guideline and pathway. Most recently, in 2021 one researcher ¹³ suggested "proper indications for shoulder subacromial decompression result in excellent outcomes" and in 2022, an expert consensus ¹⁴ of nearly 40 North American and European surgeons declared that surgery was indicated for patients who have failed nonoperative treatment for a minimum of 6 months.

Cheshire and Merseyside Integrated Care Board

5.14 On balance, therefore, until new evidence comes to light it is suggested that the current policy of routinely commissioning for "appropriate cases" should be maintained. Similar policies are in place for all other neighbouring CCGs. The crucial decision is to decide what constitutes "appropriate". The criteria in the "recommended policy statement" have been developed largely according to BOA/BESS guidelines and local surgical opinion.

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6. Advice and Guidance

6.1 Aim and Objectives

- 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.
- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.
- 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.
- At the time of publication, the evidence presented per procedure/treatment was the most current available.
- 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.
- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- 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.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- 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 available on the C&M ICB website: <u>https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/</u>

6.4 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: <u>http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx</u> and <u>http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx</u>

6.5 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.

6.6 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.

7. Monitoring and Review

- 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.
- 7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

- 7.3 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
- 7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

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

9. Clinical Coding

9.1 See Evidence Based Interventions (EBI) programme <u>https://ebi.aomrc.org.uk/resources/</u>

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