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DRAFT
**Policy for the use of
Image Guided
Therapeutic Intra-
Articular Joint Injections.**

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group 23.05.2019
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

Arthritis is a chronic musculoskeletal disorder, which may be either degenerative or inflammatory in nature and is characterised by involvement of all joint structures including the synovial membrane, cartilage and bone. People often have joint pain, reduced mobility, reduced participation in daily activities and poor quality of life [1].

The joints most commonly affected by arthritis are the knees, hips and small joints of the hand, although most joints can be affected. Pain, reduced function and effects on a person's ability to carry out their day-to-day activities can be important consequences of arthritis. Pain in itself is also a complex biopsychosocial issue, related in part to a person's expectations and self-efficacy (that is, their belief in their ability to complete tasks and reach goals), and is associated with changes in mood, sleep and coping abilities. There is often a poor link between changes visible on an X-ray and symptoms of arthritis: minimal changes can be associated with a lot of pain, or modest structural changes to joints can occur with minimal accompanying symptoms [2].

Contrary to popular belief, arthritis is not just caused by ageing and does not necessarily deteriorate. It is believed that a variety of traumas and inflammation may trigger the need for a joint to repair itself which may result in a structurally altered but symptom-free joint. However, in some people, because of either overwhelming trauma or ongoing inflammation or compromised repair, the process cannot fully compensate, resulting in eventual presentation with symptomatic arthritis.

Treatment options

A range of lifestyle, pharmacological, non-pharmacological, surgical and rehabilitation interventions are effective for controlling symptoms and improving function in both degenerative and inflammatory arthritis (NICE 2012) Conventional conservative therapies include the use of simple analgesics, non-steroidal anti-inflammatory drugs, physical therapy and intra-articular (IA) corticosteroid administration [3].

NICE published Clinical Guideline (CG177) - Osteoarthritis: care and management in February 2014 [2]. The guidelines made the following recommendations regarding intra-articular injections;

- Intra-articular corticosteroid injections should be considered as an adjunct to core treatments for the relief of moderate to severe pain in people with osteoarthritis.
- Do not offer intra-articular hyaluronan injections for the management of osteoarthritis.

Intra-articular injections of corticosteroids have been used for several decades in the management of inflammatory and degenerative joint conditions when first line conservative therapies fail to provide adequate symptom relief [4].

Intra-articular injections are performed using anatomical landmarks to identify the correct trajectory for needle placement. However, inaccurate corticosteroid injections may result in complications such as post-injection pain, crystal synovitis, haemarthrosis, and steroid articular cartilage atrophy, as well as systemic effects, including fluid retention or exacerbation of hypertension or diabetes mellitus. Therefore, identification of methods and proper training to aid in correct needle placement during these procedures is warranted [4, 6].

The purpose of image guidance during corticosteroid joint injections is to allow visualisation, normally of the joint line typically in real time, so that the operator can achieve potentially safer and more effective injection [4, 5].

Clinical Evidence Review.

No high-quality evidence to support the clinical effectiveness of image guided intra-articular corticosteroid injections, compared to non-image guided intra-articular corticosteroid injections, was found, although some lower quality evidence was found.

Evidence from a low quality study (retrospective chart review) [14] suggests that ultrasound guided intra-articular corticosteroid injections for osteoarthritis of the AC joint significantly improves some clinical outcome measures (VNSIp score and SPADI score at six months and VNSaat score at three months and six months), compared to palpation guided intraarticular corticosteroid injections. The clinical relevance of the difference seen in these outcome measures is uncertain.

In addition, a moderate quality study (single-blinded RCT) [16] also suggests that sonographic guided intra-articular corticosteroid injections significantly improves pain relative to palpation guided injections in patients with osteoarthritis of the knee after two weeks (although this was not sustained at six months follow-up), reduces reinjection rates within 12 months and increases the time to the next procedure. However, the lack of blinding of the participants to the treatments they received means that there was potential for bias in the results.

These findings conflict with those from a moderate quality prospective single-blinded randomised controlled study [15] which reported no difference in the clinical outcomes measured between US guided and palpation guided intra-articular corticosteroid injections for patients with distal radioulnar joint disorder (DRUJ).

Evidence from this study of distal radioulnar joint disorder (DRUJ) injections [15] suggests that US guided intra-articular corticosteroid injections into the distal radioulnar joint (DRUJ) have a higher accuracy rate relative to palpation guided intra-articular corticosteroid injections (100% versus 75%; $p < 0.05$). The authors also suggest a positive correlation between accuracy and improvement in clinical outcomes measured ($p < 0.05$). However, the study may not have been sufficiently powered to show any differences between outcomes for US guided compared to palpation guided injections due to the relatively small number of inaccurate injections in the latter group.

Conclusion

In conclusion there was not a significantly robust evidence base to support the use of image-guidance in delivering intra-articular joint injections.

However, the use of image guidance for hip and spinal intra-articular injections are outside the scope of this policy.

Eligibility Criteria

Therapeutic image guided intra-articular corticosteroid injections are **Restricted**.

Therapeutic image guided intra-articular corticosteroid injections should only be undertaken in the small joints (defined as joint of the hands & feet)

AND

Therapeutic image guided intra-articular corticosteroid injections should be offered **ONLY** to patients who have failed to respond to conventional pharmacological and non-pharmacological interventions due to the limited quality of evidence of the clinical and cost effectiveness of this intervention.

Pharmacological and non-pharmacological interventions are defined as:

- Analgesics/nonsteroidal anti-inflammatory drugs (NSAIDs)
- Domestic exercise programme
- Supervised physiotherapy/manual therapy
- Non-image guided (palpated) steroid injections

N.B.

- Diagnostic image –guided injections are not within the remit of this policy.
- The use of image guidance for hip and spinal intra-articular injections is outside the remit of this policy.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should be investigated in line with the relevant cancer pathway.

Guidance

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DRAFT

**Policy for the use of
Image Guided High
Volume
Intra-Articular Injections.**

Document Details:

Version:	DRAFT v1.
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group 23.05.2019
Date issued for Public Consultation:	02.09.2019
Equality & Diversity Impact Assessment	25.11.2019
Governing Board	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

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6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
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Category: Not Routinely Commissioned

Joint Pain

Pain in the joints affects millions of people worldwide. The causes of joint pain are numerous. Joint pain can be related to osteoarthritis or inflammatory joint disorders such as rheumatoid arthritis and psoriatic arthritis. Joint pain can also be as a result of traumatic injury, joint surgery or crystal deposition in the joints such as gout or chondrocalcinosis. Other causes of joint pain include sports injuries, general sprains and strains, frozen or unstable shoulder, and bleeding into joint spaces caused by torn ligaments.

Depending on the individual, pain might be felt in the joint or in the muscles around the joint. Depending on the cause the pain may be diffuse and constant, occurring at rest or while moving. Despite the wide range of underlying conditions and symptoms, joint pain of different aetiology may share similar mechanisms, manifestations, and potential treatments.

Image Guided High Volume Intra-Articular Injections

Treatment of joint pain consists of both pharmacologic and non-pharmacologic modalities. First-line therapy generally includes analgesia and physiotherapy.

Hydrodilatation (HD) also known as arthrographic capsular distension or distension arthrography is a procedure where a high volume injection of saline solution and/or steroids or air is given into the joint. Dependent upon the contracted state of the joint capsule, hydrodilatation usually occurs with an injection of between 10ml and 55ml of normal saline.

The procedure is performed under imaging guidance, using fluoroscopy, ultrasound or Computed Tomography (CT). Hydrodilatation is felt to provide benefit via two mechanisms: manual stretching of the capsule and thus disruption of adhesions that might be limiting the movements of the glenohumeral joint and causing pain and disability which are characteristic of adhesive capsulitis; and the introduction of cortisone, which provides a potent anti-inflammatory effect and thus prevents further recurrence of adhesion.

Clinical Evidence Review

From the evidence reviewed, there is no clear benefit of treatment for joint pain with an image-guided high volume intraarticular injection.

Evidence from two systematic reviews of Randomised Controlled Trials (RCTs) comparing hydrodilatation with corticosteroids, and corticosteroid injection only, is conflicting. The systematic review (with meta-analysis) by Saltychev et al (2018) reported that hydrodilatation with corticosteroids has only a small, clinically insignificant effect for pain and Range Of Movement (ROM) (seven RCTs) when treating adhesive capsulitis. Conversely, Catapano et al (2018) reported that the intervention is likely to be effective. However, this conclusion was based on the results from two of five RCTs and three of five RCTs which reported improvements in pain scores and range of movement respectively. The evidence is therefore at best inconsistent. No long term results were reported. Both authors report that the included RCTs were of moderate quality.

Evidence from one small RCT suggests that arthrographic capsular release is associated with a higher Oxford Shoulder Score (OSS) than hydrodilatation at six months follow-up. It is not known for how long this effect is likely to be sustained (Gallacher 2018). In addition, the study may not have been sufficiently powered to show any meaningful differences. The pain scores were reported by the patients who were not blinded to their treatment, this could have introduced bias. It is also unclear whether the Range Of Movement assessors were blinded to the treatments.

Eligibility Criteria

Due to the limited quality of evidence of clinical effectiveness for image-guided high volume intra-articular joint injections, high volume injections are Not Routinely Commissioned.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

DRAFT

Guidance

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DRAFT
**Policy for Subacromial
Pain in Adults.**

Document Details:

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Date issued for Public Consultation:	2 nd September 2019
Equality & Diversity Impact Assessment	25 th November 2019
Governing Board	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

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Category: Not Routinely Commissioned

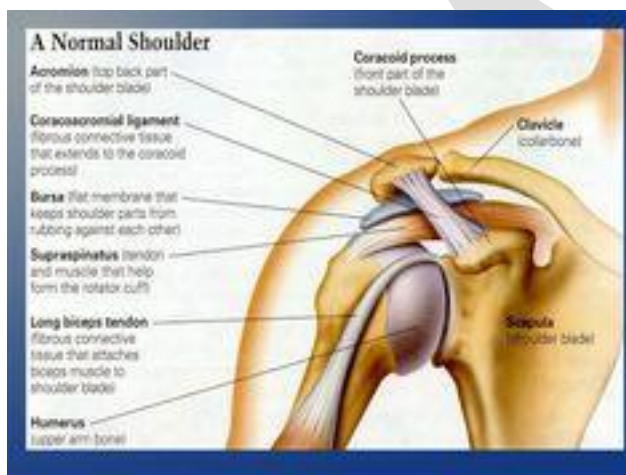
Sub-acromial Pain in Adults

Rotator cuff disease (wear and tear of the rotator cuff tendons) is thought to be a continuum ranging from shoulder impingement syndrome (SIS) through to partial and then full thickness rotator cuff tears [1]. It is one of the most common causes of non-traumatic shoulder pain which presents in primary care and is a normal part of aging [2].

The rotator cuff tendons hold the shoulder joint in place and allow people to lift the arm and reach overhead. When the arm is lifted, the rotator cuff tendon passes through a narrow space at the top of the shoulder, known as the sub-acromial space. The illustration of a healthy shoulder joint below (Figure 1) shows the relationship of tendons, ligaments, soft tissue and bony anatomy of the sub-acromial space.

Arthroscopic sub-acromial decompression is a surgical procedure that involves decompressing the sub-acromial space by removing bone spurs and soft tissue arthroscopically.

Figure 1: Anatomy of a normal shoulder.



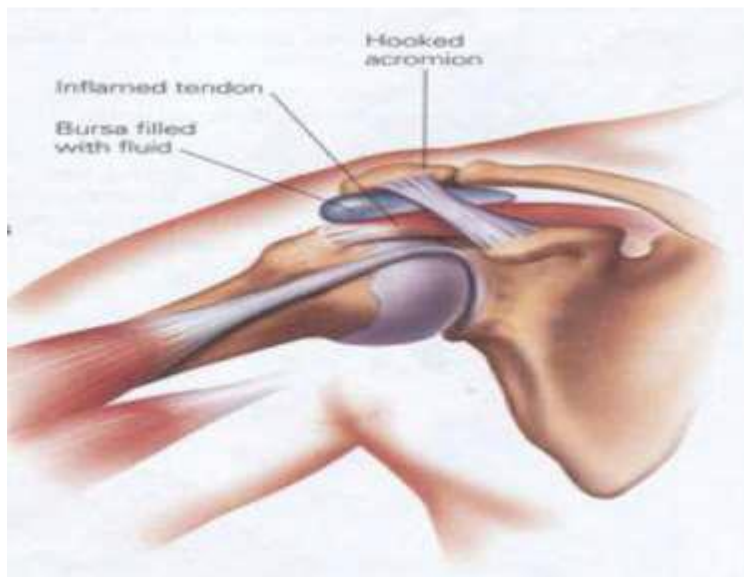
Source: Orthopaedic Surgeons of Long Island Association.

Retrieved from

http://www.orthomd.com/procedures/impingement_syndrome.html

Previously it was thought that sub acromial pain occurs when the top of the tendon rubs or catches on the acromion and the sub-acromial bursa, however more recent studies have shown that between 76-91% of rotator cuff tears occur within the tendon or on the 'under-side' of the tendon. There has been shown to be poor correlation between acromial shape and pain. Furthermore, rotator cuff tears can continue to develop post sub-acromial decompression. To this end subacromial decompression surgery is no longer recommended routinely in any clinical circumstances.

Figure 2: Anatomy of a shoulder affected by shoulder impingement syndrome



The main problem in shoulder impingement syndrome is of pain in the top and outer side of the shoulder, which is worse when the arm is raised overhead [1]. Pain is associated with dysfunction, affecting usual activities of daily living, sporting activities and ability to work full time. Patients often report a significant reduction in terms of health-related quality of life [3].

Shoulder impingement will often improve in a few weeks or months, especially with prescribed shoulder exercises.

Arthroscopic Sub-acromial Decompression.

The term 'arthroscopic' describes any surgical procedure which is performed using surgical instruments inserted through a small 'keyhole' incision and an endoscope inserted via a separate incision to visualise the area.

Arthroscopic shoulder surgery is not one single surgical procedure; rather it refers to a wide range of procedures to different parts of the shoulder anatomy. These may repair damaged cartilage or torn tendons, remove loose fragments of bone or cartilage, drain excess fluid, or release adhesions.

Arthroscopic sub-acromial decompression (ASD) is the most common surgical procedure in patients with shoulder impingement syndrome (SIS) [3]. The standard procedure is antero-inferior acromioplasty, i.e. the resection of bone spurs under the lateral third of the acromion, as well as the excision of the coracoacromial ligament and the sub-acromial bursa. If a partial or small full-thickness tear of the rotator cuff is present, it may be mildly debrided or left alone [3].

Evidence Review

Shoulder Impingement Syndrome.

Three randomised controlled trials were identified and reviewed, which compared ASD to conservative treatment for patients with SIS (at 24 months in two of the trials and 12 months only in the CSAW RCT). Patients with partial thickness rotator cuff tears were not excluded from these RCTs. The key differences between the study design were that Ketola et al [7] compared ASD plus physiotherapy to physiotherapy alone [7], whereas in the FIMPACT [6] and CSAW [4] RCTs, there were three treatment arms. Both FIMPACT and CSAW included ASD plus physiotherapy and diagnostic arthroscopy plus physiotherapy as two of the three arms. However, in the UK based multicentre RCT known as CSAW, the third arm was no treatment at all, whereas in the FIMPACT RCT, the non-operative third arm was a home exercise regime as well as 15 physiotherapy visits.

- ASD plus physiotherapy versus diagnostic arthroscopy plus physiotherapy. There was no clinically significant difference between ASD plus physiotherapy treatment compared to diagnostic (sham) arthroscopy plus physiotherapy at either 12-month follow-up in the CSAW RCT [4] or at 24 months (FIMPACT RCT) [6]. This was consistent for all of the outcomes measured: OSS, Constant score, pain, depression and anxiety, quality of life, simple shoulder test, 15D and patient satisfaction.
- ASD plus physiotherapy versus no treatment: Although small statistical differences were seen in favour of ASD followed by up to four sessions of physiotherapy, there were no clinically important differences for any outcomes measured at 12 months compared to no treatment at all [4].
- ASD plus physiotherapy versus physiotherapy therapy only: There were no clinically important differences reported between these two treatment groups at 24-month follow-up [6,7] even though the physiotherapy protocol for the FIMPACT RCT was for 15 sessions (compared to just one post-operative session for those being treated with ASD). Both the ASD plus PT and PT only groups in the RCT by Ketola et al [7] had a similar number of physiotherapy sessions (6 and 7 sessions respectively). Within each treatment group, all three trials showed clinically significant improvements at 12 or 24 months, when compared to baseline for the OSS, the Constant score and for pain [4,6,7].

These RCTs showed that ASD for SIS was no more effective than physiotherapy alone or no treatment at achieving clinically important differences at 12 months and 24 months (OSS, Constant Score and pain). In addition, all three treatment groups achieved clinically important improvements over time compared to baseline. This suggests that the natural history of non-traumatic shoulder impingement syndrome, which has previously failed conservative treatment, is for the painful and disabling symptoms to resolve without intervention.

Supraspinatus tear.

There was one single RCT where 180 patients with a supraspinatus tear were treated with arthroscopic acromioplasty and physiotherapy, or tendon repair, acromioplasty and physiotherapy and the outcomes were compared to patients who had 10 sessions of physiotherapy alone. All the patients followed the same physiotherapy plan. There were no between group differences in the Constant score at 12 months. Although the ASD was performed concomitantly with repair of the supraspinatus tendon, the results are consistent with the results of the RCTs which assessed the effectiveness of ASD for the management of shoulder impingement syndrome.

Cost Effectiveness.

No studies generalisable to the NHS were found which measured the cost effectiveness of ASD compared to conservative treatment in patients with subacromial shoulder pain.

Conclusion

There has been shown to be poor correlation between acromial shape and pain. Furthermore, rotator cuff tears can continue to develop post sub-acromial decompression. There is no evidence that ASD offers any better outcome than more conservative options. Subacromial decompression surgery is therefore no longer recommended in any clinical circumstances.

Eligibility Criteria

Due to the lack of evidence for the clinical effectiveness of arthroscopic shoulder decompression (ASD) compared to conservative treatment, ASD in any clinical circumstances, is not routinely commissioned.

N.B. Acute Severe Shoulder Pain

- Any shoulder 'red flags' identified during primary care assessment need urgent secondary care referral. A suspected infected joint needs same day emergency referral.
- An unreduced dislocation needs same day emergency referral.
- Suspected tumour and malignancy will need urgent referral following the local 2-week cancer referral pathway.
- An acute cuff tear as a result of a traumatic event needs urgent referral and ideally should be seen in the next available outpatient clinic.
- Acute calcific tendinopathy is not a red flag, it is severely painful, often mimicking malignant pain and usually necessitates an early secondary care referral.
- It should also be noted that patients with subacromial shoulder pain in which the symptoms and signs suggest a more systemic inflammatory joint disease, should be considered as a 'rheumatological red flag'.
- Any new inflammatory oligo or polyarthritis, with symptoms of inflammation in several joints, should be referred urgently (following local rheumatology referral pathways) because time is of the essence with these diseases and a prompt diagnosis with early commencement of disease modifying drugs where appropriate is essential.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

N.B. investigation for suspected or proven malignancy is outside the scope of this policy and should be investigated in line with the relevant cancer pathway.

Guidance

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