NHS
Cheshire and Merseyside

# Clinical Commissioning Policy

## Osteoarthritic induced changes in peripheral joints (knee, hips, ankle & thumb), intra-articular hyaluronan (hyaluronic acid)

### Category 1 Intervention - Not routinely commissioned -

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| Version: | 1 |
| Purpose | This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite. |
| Supersedes: | Previous Clinical Commissioning Group (CCG) Policy |
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| **Document control:** | | |
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# 1. Introduction

1.1 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

1.2 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 in Appendix 1.

1.3 At the time of publication, the evidence presented per procedure/treatment was the most current available.

# 2. Purpose

2.1 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.

# 3. Policy statement

3.1 Intra-articular hyaluronan is not routinely commissioned for injection into the peripheral joints of the knee, hips, ankle & thumb.

# 4. Exclusions

4.1 None

# 5. Rationale

5.1 NICE guideline CG 177 recommended against the use of intra-articular hyaluronan in the management of osteoarthritis.

5.2 This policy position has subsequently been confirmed with the publication of the updated version of this guideline (NG 226) in October 2022.

# 6. Underpinning evidence

6.1 Osteoarthritis is a syndrome which consists of joint pain accompanied by varying degrees of functional limitation and reduced quality-of-life. The most commonly affected peripheral joints are the knees, hips, ankle and thumb.[1] Progressive loss of a particular cartilage may result and there is no curative treatment.[2] Available therapies include physiotherapy, weight loss, lifestyle changes, steroid injections and intra-articular hyaluronic acid. The knee is the leading cause of disability in older adults and more than a third of people aged over 60 years have radiographic evidence of knee osteoarthritis.[3]

6.2 Endogenous *hyaluronan* (previously known as hyaluronic acid or hyaluronate) is a large, linear structure which is a major component of both the synovial and cartilage extracellular matrix. Its key functions in the joint are to confer viscoelasticity, lubrication and help maintain tissue hydration and protein homeostasis by preventing large fluid movements and by acting as an osmotic buffer.[1] The mechanism of action of exogenously administered hyaluronan isn't certain.

6.3 Over the last 20 years, the efficacy of intra-articular hyaluronan (particularly in the knee) has been questioned. Most recently, a systematic review which compared hyaluronan with oral NSAIDs for the knee, concluded that in the short term the intra-articular injections provided improvement which may have been statistically significant yet clinically insignificant.[3] It has frequently been suggested that the majority of the "benefit" is mediated by a placebo effect.[4,5] In contrast, a 2021 economics review concluded that hyaluronan was cost-effective against NSAIDs, corticosteroids, analgesics and other conservative treatment. However, this was largely a narrative review which failed to critically appraise the cited retrospective studies in terms of quality (which was not stated) and neither was a meta-analysis conducted.[2]

6.4 In terms of national guidance, perhaps the most authoritative guideline is in NICE's CG 177.[1] This guideline on osteoarthritis was published in 2014 and replaces CG 59 (2008). Recommendation 1.5.13 states "do not offer intra-articular hyaluronan injections for the management of osteoarthritis."

6.5 Since then, a 2021 review which compared 27 clinical practice guidelines identified conflicting recommendations.[6] However, the American Academy of orthopaedic surgeons working group recommended against using hyaluronan injection for relief of osteoarthritis of the knee.[7] Most recently (October 2022), CG 177 was replaced by NG 226 which similarly states that intra-articular hyaluronan injections should not be offered in the treatment of osteoarthritis.[8]

6.6 In summary, intra-articular hyaluronan (sometimes called hyaluronic acid or hyaluronate) has been used to treat pain and dysfunction of the peripheral joints such as the knees (mainly), hips, ankle and thumb. The underlying problem is osteoarthritic changes which results in destruction of the cartilage although the mechanism as to how hyaluronan works isn't certain. For over 20 years, the efficacy of this intervention has been questioned. However, NICE's Clinical Guideline (CG 177) makes a firm recommendation that intra-articular hyaluronan should not be used in the management of osteoarthritis. This is supported by the American Academy of orthopaedic surgeons and is also confirmed by the updated version of CG 177 which was published in October 2022.

6.7 Neighbouring CCGs either have no policy or the intervention is not routinely commissioned.

**REFERENCES**


**1**. Osteoarthritis: care and management. Clinical guideline. London: National Institute for Health and Care Excellence, 2014 (Updated 2020):CG177.

**2**. Mordin M, Parrish W, Masaquel C, et al. Intra-articular Hyaluronic Acid for Osteoarthritis of the Knee in the United States: A Systematic Review of Economic Evaluations. *Clinical medicine insights Arthritis and musculoskeletal disorders* 2021;**14**:1-13. doi: https://dx.doi.org/10.1177/11795441211047284

**3**. Miller LE, Fredericson M, Altman RD. Hyaluronic Acid Injections or Oral Nonsteroidal Anti-inflammatory Drugs for Knee Osteoarthritis: Systematic Review and Meta-analysis of Randomized Trials. *Orthopaedic journal of sports medicine* 2020;**8**(1):1-11. doi: https://dx.doi.org/10.1177/2325967119897909

**4**. Richardson C, Plaas A, Block JA. Intra-articular Hyaluronan Therapy for Symptomatic Knee Osteoarthritis. *Rheumatic diseases clinics of North America* 2019;**45**(3):439-51. doi: https://dx.doi.org/10.1016/j.rdc.2019.04.011

**5**. Maheu E, Bannuru RR, Herrero-Beaumont G, et al. Why we should definitely include intra-articular hyaluronic acid as a therapeutic option in the management of knee osteoarthritis: Results of an extensive critical literature review. *Seminars in arthritis and rheumatism* 2019;**48**(4):563-72. doi: https://dx.doi.org/10.1016/j.semarthrit.2018.06.002

**6**. Phillips M, Bhandari M, Grant J, et al. A Systematic Review of Current Clinical Practice Guidelines on Intra-articular Hyaluronic Acid, Corticosteroid, and Platelet-Rich Plasma

Injection for Knee Osteoarthritis: An International Perspective. *Orthopaedic journal of sports medicine* 2021;**9**(8):1-9. doi: https://dx.doi.org/10.1177/23259671211030272

**7**. Lyon C, Spencer E, Spittler J, et al. Clinical Inquiries: How do hyaluronic acid and corticosteroid injections compare for knee OA relief? *The Journal of family practice* 2018;**67**(1):E13-E14.

**8**. Osteoarthritis in over 16s: diagnosis and management. NICE guideline. London: National Institute for health and care excellence, 2022:NG226.

# 7. Force

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.

# 8. Coding

8.1 **Office of Population Censuses and Surveys (OPCS)**
**In primary position only**
W903 Injection of therapeutic substance into joint

8.2 **International classification of diseases (ICD-10)**
None

# 9. Monitoring And Review

9.1 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

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

# 10. Quality and Equality Analysis

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

# Appendix 1 - Core Objectives and Principles

## Objectives

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.

## Principles

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.

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.

## Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

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 wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

# 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:
http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and
http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

# 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.

# 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.

# Clinical Exceptionality

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.