

Greater Manchester EUR Policy Statement on:

Hyaluronic Acid Injections for Osteoarthritis

GM Ref: GM037

Version: 3.1 (25 January 2019)

Commissioning Statement

Hyaluronic Acid Injections for Osteoarthritis	
Policy Exclusions (Alternative commissioning arrangements apply)	Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).
Policy Inclusion Criteria	<p>Hyaluronic acid injections are <u>not</u> routinely commissioned for osteoarthritis, particularly osteoarthritis of the knee.</p> <p>Funding Mechanism</p> <p>Clinicians can submit an individual funding request outside of this guidance if they feel there is a good case for clinical exceptionality. Requests <u>must</u> be submitted with all relevant supporting evidence.</p>
Clinical Exceptionality	<p>Exceptionality means ‘a person to which the general rule is not applicable’. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:</p> <ul style="list-style-type: none"> Significantly different to the general population of patients with the condition in question. <p>and as a result of that difference</p> <ul style="list-style-type: none"> They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.
Best Practice Guidelines	All providers are expected to follow best practice guidelines (where available) in the management of these conditions.

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Policy Statement

Greater Manchester Health and Care Commissioning (GMHCC) Effective Use of Resources (EUR) Policy Team, in conjunction with the GM EUR Steering Group, have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMHCC/GM EUR Steering Group have reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

Equality & Equity Statement

GMHCC/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMHCC/CCGs are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMHCC/CCGs will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMHCC EUR Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMHCC evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact policyfeedback.gmscu@nhs.net.

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Joint Commissioning Board (GMJCB) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the [GM EUR Operational Policy](#).

Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

Rationale behind the policy statement

As both NICE and the BNF state that these injections should not be used, based on their reviews of the available evidence they are not commissioned by Greater Manchester CCGs.

The Greater Manchester Medicines Management Group (GMMMMG) have also assessed Sodium hyaluronate injection against the GMMMMG wide 'Do Not Prescribe' list criteria and the group concluded that sodium hyaluronate products used for injection into the knee for the relief of osteoarthritis should be included in the GMMMMG 'Do not Prescribe' List.

Treatment / Procedure

Hyaluronic acid injections for osteoarthritis are offered for the relief of joint pain but are not considered to be effective in osteoarthritis, particularly of the knee. Some patients have had these injections with some improvement previously, however NICE CG59 (superseded by NICE CG177) clearly states "do not do" in relation to this treatment.

Hyaluronic acid is injected intra-articularly to supplement natural hyaluronic acid in the synovial fluid. These injections may reduce pain over 1-6 months, but are associated with a short-term increase in knee inflammation. There are a number of products available but the commonest requested version is *Ostenil*®.

Epidemiology and Need¹

The exact incidence and prevalence of osteoarthritis is difficult to determine because the clinical syndrome of osteoarthritis (joint pain and stiffness) does not always correspond with the structural changes of osteoarthritis (usually defined as abnormal changes in the appearance of joints on radiographs). This area is becoming more complex with sensitive imaging techniques such as magnetic resonance imaging, which demonstrate more frequent structural abnormalities than detected by radiographs. Osteoarthritis at individual joint sites (notably knee, hip and hand) demonstrates consistent age-related increases in prevalence (Arthritis and Musculoskeletal Alliance 2004). However, symptomatic osteoarthritis is not an inevitable consequence of ageing. Although prevalence of osteoarthritis rises in frequency with age, it does affect substantial numbers of people of working age. The number of people with osteoarthritis in the UK is increasing as the population ages, and as the prevalence of risk factors such as obesity and poor levels of physical fitness also continues to rise.

Adherence to NICE Guidance

This adheres to NICE CG177: Osteoarthritis: care and management.

Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

¹ Source: NICE

Date of Review

Five years from the date of the last review, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

Glossary

Term	Meaning
BNF	British National Formulary
Greater Manchester Medicines Management Group (GMMMGM)	The GMMMGM is the coordinating group for decision making around medicines and in particular high cost medicines for Greater Manchester. It also has a role in performance monitoring of health economies prescribing.
Hyaluronic Acid	A synthetic version of the gel like aminoglycan that is found in the tissue space, the synovial fluid of joints and acts as a binding, lubricating, and protective agent.
NICE	National Institute for Health and Care Excellence
Osteoarthritis	Degeneration of joint cartilage and the underlying bone, most common from middle age onward.
SIGN	Scottish Intercollegiate Guidelines Network

References

1. Greater Manchester Effective Use of Resources Operational Policy
2. NICE CG59 and subsequent revised guidance NICE CG177
3. Osteoarthritis: The care and management of osteoarthritis in adults, National Institute of Health and Care Excellence Clinical Guideline 59, February 2008
4. NICE CG177: Osteoarthritis: care and management (Published: February 2014)
5. [Osteoarthritis and soft-tissue disorders, British National Formulary](#) [accessed 10/09/2013] 35TU
6. [National Institute of Health and Care Excellence 'Do not Do' Recommendation](#) [accessed 10/09/2013]
7. Greater Manchester Medicines Management Group 'Do Not Prescribe' List (20/11/2013)

Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	19/03/2014
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	13/05/2014
Greater Manchester Association Governing Group	03/06/2014

Bolton Clinical Commissioning Group	27/06/2014
Bury Clinical Commissioning Group	02/07/2014
Heywood, Middleton & Rochdale Clinical Commissioning Group	18/07/2014
Central Manchester Clinical Commissioning Group	03/09/2014
North Manchester Clinical Commissioning Group	11/06/2014
Oldham Clinical Commissioning Group	03/07/2014
Salford Clinical Commissioning Group	09/06/2014
South Manchester Clinical Commissioning Group	25/06/2014
Stockport Clinical Commissioning Group	10/09/2014
Tameside & Glossop Clinical Commissioning Group	21/05/2014
Trafford Clinical Commissioning Group	15/07/2014
Wigan Borough Clinical Commissioning Group	18/06/2014

Appendix 1 – Evidence Review

Hyaluronic Acid Injections for Osteoarthritis GM037

Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; BMJ Clinical Evidence; and the relevant Royal College websites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

Database	Result
NICE	NICE CG177: Osteoarthritis: care and management Do Not Do Recommendation (Published date: February 2014)
British National Formulary (BNF)	Osteoarthritis and soft-tissue disorders [accessed 10/09/2013]

Summary of the evidence

The original search was carried out using NHS evidence, NICE Guidance, Scottish Intercollegiate Guidelines Network (SIGN) and the British National Formulary (BNF).

As this procedure was on the NICE “do not use” list, and the BNF stated “should not be used in osteoarthritis of the knee” no further search for evidence of effectiveness was carried out.

The search was repeated for the scheduled policy reviews in April 2015 and April 2017. The evidence of effectiveness for this intervention is still very low quality and the benefit does not appear to outweigh the potential risks.

The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

1. LEVEL: N/A

British National Formulary (BNF): Osteoarthritis and soft-tissue disorders [accessed 10/09/2013]

Hyaluronic acid and its derivatives are available for osteoarthritis of the knee, but are not recommended. Sodium hyaluronate (*Durolane*®, *Euflexxa*®, *Fermathron*®, *Orthovisc*®, *Ostenil*®, *Ostenil Plus*®, *RenhaVis*®, *Suplasyn*®, *Synocrom*®, *Synopsis*®) or hylan G-F 20 (*Synvisc*®) is injected intra-articularly to supplement natural hyaluronic acid in the synovial fluid. These injections may reduce pain over 1–6 months, but are associated with a short-term increase in knee inflammation. Sodium

hyaluronate (*SportVis*®) is also licensed for the relief of pain and optimisation of recovery following ankle sprain, and for the relief of chronic pain and disability associated with tennis elbow.

2. LEVEL: N/A

NICE Guidance CG177: Osteoarthritis: care and management, Date reviewed: April 2015

Intra-articular injections

1.5.12 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. **[2008]**

1.5.13 **Do not offer** intra-articular hyaluronan injections for the management of osteoarthritis. **[2014]**

Appendix 2 – Diagnostic and Procedure Codes

Hyaluronic Acid Injections for Osteoarthritis GM037

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

GM037 - Hyaluronic Acid Injections	
The following OPCS-4 codes are not specific to hyaluronic acid injections but might be a way of creating a data set to audit separately:	
Injection of therapeutic substance into joint; plus one of the following site codes	W90.3
Patellofemoral joint	Z84.4
Tibiofemoral joint	Z84.5
Knee joint	Z84.6
With the following ICD-10 diagnosis code(s):	
Primary generalized (osteo)arthrosis	M15.0
Heberden nodes (with arthropathy)	M15.1
Bouchard nodes (with arthropathy)	M15.2
Secondary multiple arthrosis	M15.3
Erosive (osteo)arthrosis	M15.4
Other polyarthrosis	M15.8
Polyarthrosis, unspecified	M15.9
Primary gonarthrosis, bilateral	M17.0
Other primary gonarthrosis	M17.1
Post-traumatic gonarthrosis, bilateral	M17.2
Other post-traumatic gonarthrosis	M17.3
Other secondary gonarthrosis, bilateral	M17.4
Other secondary gonarthrosis	M17.5
Gonarthrosis, unspecified	M17.9

Appendix 3 – Version History

Hyaluronic Acid Injections for Osteoarthritis GM037

The latest version of this policy can be found here [GM Hyaluronic Acid Injections for Osteoarthritis policy](#)

Version	Date	Summary of Changes
0.1	09/09/2013	Initial draft
0.2	19/09/2013	Inclusion of additional criteria following discussion at the GM EUR Steering Group meeting on 18/09/2013 relating to patients who have previously had this treatment
0.3	09/09/2013	<ul style="list-style-type: none"> Inclusion of advice from Sarah Jacobs, Senior Strategic Pharmacist, GMCSU to state that this treatment is on the GMMMG 'do not prescribe' list. Removed reference to number of IFRs received.
0.4	17/10/2013	Absence of Evidence Summary added.
0.5	28/11/2013	<ul style="list-style-type: none"> Decision to remove criteria relating to 'ongoing care' made by the GM EUR Steering Group on the 20/11/2013, following a GMMMG recommendation made on the 3/10/2013 to add Sodium Hyaluronate Injection to the GMMMG 'Do not Prescribe' List Reference list updated.
	29/11/2013	Policy consultation.
	19/03/2014	Policy approved by GM EUR Steering Group subject to review of wording relating to NICE and BNF to ensure it is compliant with the relevant guidance and review of additional references provided through consultation feedback.
0.6	08/04/2014	<ul style="list-style-type: none"> Removal of '<i>or where individual sustained benefit can be proven</i>' from section 9, mechanism for funding, as this related to the previous amendment regarding 'ongoing care', in version 0.5 and should have been removed at that time. Amendment to the wording in section 6, evidence summary, second paragraph to reflect NICE/BNF guidance, as recommended by GM EUR Steering Group on 19/03/2014. Reference to revised NICE guidance, CG 177 added. Removal of 'of the knee' from the policy title.
1.0	13/05/2014	Approved at Greater Manchester Heads of Commissioning and Greater Manchester Chief Finance Officers
	03/06/2014	Approved at Greater Manchester Association Governing Group
2.0	25/06/2015	Changes made following annual review by GM EUR Steering Group on 20 May 2015: <ul style="list-style-type: none"> Branding change to North West CSU Section 7: Absence of Evidence Summary replaced by Review of the Evidence
2.1	05/04/2016	<ul style="list-style-type: none"> List of diagnostic and procedure codes in relation to this policy added as Appendix 1. Policy changed to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.

		<ul style="list-style-type: none"> • <u>Date of Review and Policy Statement:</u> Wording for date of review amended to read <i>“One year from the date of approval by Greater Manchester Association Governing Group thereafter at a date agreed by the Greater Manchester EUR Steering Group (unless stated this will be every 2 years)”</i>
2.2	14/12/2016	<p><u>Appendix 1:</u> Removed all procedure codes that are not related to knee joints.</p>
3.0	17/05/2017	<p>GM EUR Steering Group reviewed the policy and agreed that no changes were necessary as the evidence of effectiveness for this intervention is still very low quality. The group agreed that the policy would be reviewed again in 5 years unless new evidence is available sooner.</p> <ul style="list-style-type: none"> • <u>Date of Review:</u> Section amended to state: <i>'Five years from the date of the last review, unless new evidence is available sooner. The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.'</i> • <u>Appendix 1: Evidence Review:</u> <ul style="list-style-type: none"> ○ Links updated on the search database under <i>'Search Strategy'</i> ○ Under <i>'Summary of the evidence'</i> the sentence <i>'The search was repeated for the scheduled policy review in April 2015.'</i> was amended to read: <i>'The search was repeated for the scheduled policy reviews in May 2015 and April 2017.'</i>
3.1	25/01/2019	<ul style="list-style-type: none"> • Branding changed to reflect change of service from Greater Manchester Shared Services to Greater Manchester Health and Care Commissioning. • Links updated as documents have all moved to a new EUR web address. • <u>Commissioning Statement:</u> <ul style="list-style-type: none"> ○ <i>'(Alternative commissioning arrangements apply)'</i> added after Policy Exclusions ○ <i>'Best Practice Guideline'</i> section added