



Greater Manchester EUR Policy Statement on:

Facet Joint Injections for Neck and Back Pain

GM Ref: GM070 Version: 2.2 (25 January 2019)

Commissioning Statement

	Facet Joint Injections for Neck and Back Pain
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	New Patients: Lumbar
Criteria	 Facet joint injections are commissioned for patients who meet the following criteria: The back pain has been present for more than 1 year and all chronic pain management pathways have failed
	ANDthe main source of pain is thought to come from structures supplied by the medial
	branch nerve AND
	 they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral AND
	• there is no other treatment option available for the patient (i.e. non-surgical treatment has not worked for them)
	 OR alternative treatments such as analgesic medication are intolerable or produce undesirable side effects
	 OR the patient has demonstrated failure to respond to, or had a loss of response to, other treatment options
	ORother treatment options are contraindicated and this is clearly documented
	 Wherever possible patients should be encouraged to: participate in mobilisation or rehabilitation therapy
	 take effective pain relief medication
	 where indicated (and where it is available) be referred for weight management support
	If new patients gain relief from facet joint injections <u>AND</u> are suitable for radiofrequency denervation <u>AND</u> have a positive response to facet joint injections they should be referred for radiofrequency denervation.
	Funding Mechanism Individual prior approval for <u>2 injections per year</u> provided the patient meets the above criteria. Requests <u>must</u> be submitted with all relevant supporting evidence.
	If the patient does not meet the criteria: an individual funding request can be made if there is a good case for clinical exceptionality. Requests <u>must</u> be submitted with all relevant supporting evidence.

New Patients: Thoracic

Facet joint injections are commissioned provided:

• the criteria for 'New Patients: Lumbar' is met

AND

- all other treatment options have been exhausted
- AND
- the risks of facet joint injections have been fully explained to the patient.

Repeat facet joint injections may be given for patients requiring injection into thoracic facet joints but treatment is limited to no more than 2 injections a year. The interval between injections should be at least 6 months but ideally be no more frequent than 8-12 month intervals.

Funding Mechanism

Individual prior approval for <u>2 injections per year</u> provided the patient meets the above criteria. Requests <u>must</u> be submitted with all relevant supporting evidence.

<u>If the patient does not meet the criteria:</u> an individual funding request can be made if there is a good case for clinical exceptionality. Requests <u>must</u> be submitted with all relevant supporting evidence.

New Patients: Cervical

Facet joint injections are commissioned provided:

• all other treatment options have been exhausted

AND

• the risks of facet joint injections have been fully explained to the patient.

Repeat facet joint injections may be given for patients requiring injection into cervical facet joints but treatment is limited to no more than 2 injections a year. The interval between injections should be at least 6 months but ideally be no more frequent than 8-12 month intervals.

Funding Mechanism

Individual prior approval for <u>2 injections per year</u> provided the patient meets the above criteria. Requests <u>must</u> be submitted with all relevant supporting evidence.

<u>If the patient does not meet the criteria:</u> an individual funding request can be made if there is a good case for clinical exceptionality. Requests <u>must</u> be submitted with all relevant supporting evidence.

Sacroiliac joint pain

If conservative management has failed and sacroiliac joint pain is elicited using a provocation test, consider image guided sacroiliac joint injection.

If the SI injection successfully relieves pain for more than 5 months then the patient can be referred for Radiofrequency denervation or consider referral for minimally invasive sacroiliac joint fusion in line with <u>NICE IPG578</u>.

NOTE: Minimally invasive SI joint fusion is a technically challenging procedure and should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.

Extract from NICE IPG578 (for ease of reference):

- '1.1 Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.
- 1.2 Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.
- 1.3 This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.'

Funding Mechanism

<u>Image guided sacroiliac joint injections:</u> Individual prior approval provided the patient meets the above criteria. Clinicians <u>must</u> provide evidence of the result of the provocation test **OR** evidence of degenerative sacroiliitis. **NOTE:** When individual prior approval is given for the sacroiliac joint injection, individuals are already considered to have prior approval for radiofrequency denervation provided the injection gave a positive response.

<u>Sacroiliac joint fusion:</u> Individual prior approval provided the patient meets the above criteria. Clinicians <u>must</u> provide evidence of the result of the provocation test **OR** evidence of degenerative sacroiliitis **AND** the outcome of any diagnostic injection(s) **AND/OR** the outcome from RFD as applicable to the case.

Current Patients

Facet joint injections will continue to be commissioned for existing patients provided there is a demonstrable improvement in quality of life measures following each treatment. This should be assessed using a validated research tool.

Treatments should only continue where alternative treatments such as analgesic medication are intolerable or produce undesirable side effects, such as unsteadiness in the elderly.

If treatment with facet joint injections has been successful on more than two occasions, then suitable individuals should be referred for radiofrequency denervation.

However if an individual is considered to be unsuitable for radiofrequency denervation for reasons including but not limited to:

- The presence of comorbidities that contraindicate radiofrequency denervation
- Access or other anticipated mechanical difficulties in the delivery of radiofrequency denervation
- Inability of the patient to adopt or maintain the required position for the safe delivery of radiofrequency denervation

Then facet joint injections can be continued provided that treatment is limited to no more than 2 injections a year. The interval between injections should be at least 6 months but ideally be no more frequent than 8-12 month between FJIs.

Facet joint injections should **NOT** be administered if at least one of the following apply:

• there is evidence of a local or systemic infection

	 the patient is receiving substantial therapeutic or constitutional anticoagulation the patient is unwilling or is demonstrating a lack of cooperation All patients who are suitable for radiofrequency denervation should be referred after 2 successful facet joint injections <u>OR</u>, where the diagnosis is clear and a single facet joint injections supports the diagnosis, patients may be referred following 1 injection. Funding Mechanism Monitored approval: <u>but it will be expected that patients will have no more than 2 injections per year</u>. Referrals may be made in line with the criteria without seeking funding. NOTE: May be the subject of contract challenges and/or audit of cases against commissioned criteria. Diagnostic Facet Joint Injections Commissioned for patients being assessed for radiofrequency denervation. NOT commissioned for any other diagnostic use.
	Funding Mechanism Patients being assessed for radiofrequency denervation: Individual prior approval in line with the <u>GM Radiofrequency Denervation for Back Pain</u> . Requests <u>must</u> be submitted with all relevant supporting evidence. NOTE: Patients given prior approval for 2 diagnostic injections will be considered to have prior approval for radiofrequency denervation if the response to both injections is positive. Any other diagnostic use of facet joint injections: Individual funding request (exceptional case) approval: Requests <u>must</u> be submitted with all relevant supporting evidence.
Clinical Exceptionality	 Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality. 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: Significantly different to the general population of patients with the condition in question. and as a result of that difference 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 <u>policyfeedback.gmscu@nhs.net</u>.

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 <u>GM EUR Operational Policy</u>.

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

NICE guidance and other systematic reviews have highlighted the lack of evidence of effectiveness for this procedure for back pain. In light of this evidence facet joint injections for back pain is restricted to patients meeting certain criteria only.

Treatment / Procedure

Facet joints are the small joints located between each vertebra that provide the spine with both stability and flexibility. Facet joint injections combine a local anaesthetic and a corticosteroid anti-inflammatory medication. Initially, a local anaesthetic is applied, then a small spinal needle is inserted into the facet joint, and anaesthetic and medication are injected using fluoroscopic (x-ray) guidance.

The evidence of effectiveness for facet joint injections for back and neck pain is equivocal at present and further high quality studies are needed to determine its effectiveness. This policy complies with the advice in NICE NG59 (Low back Low back pain and sciatica in over 16s: assessment and management) and as a result facet joint injections for back and neck pain are commissioned for specific patient groups only unless part of a recognised trial or within a locally agreed care pathway.

Facet joint injections combine a local anaesthetic and a corticosteroid anti-inflammatory medication. The treatment is injected (the forcing of a liquid into a part) into the facet joint (the sliding joints allowing the vertebrae of the spine to glide over one another without losing contact) with the intent to alleviate chronic pain in that joint.

Back pain is a common problem that affects most people at some point in their life. It may be triggered by bad posture while sitting or standing, bending awkwardly, or lifting incorrectly. It's not generally caused by a serious condition. In most cases, back pain will improve in a few weeks or months, although some people experience long-term pain or pain that keeps coming back.

Neck pain is the fourth leading cause of disability, with an annual prevalence rate exceeding 30%. Most episodes of acute neck pain will resolve with or without treatment, but nearly 50% of individuals will continue to experience some degree of pain or frequent occurrences.

Sacroiliac joint pain: The sacroiliac joint lies next to the bottom of the spine, below the lumbar spine and above the tailbone (coccyx). It connects the sacrum (the triangular bone at the bottom of the spine) with the pelvis (iliac crest). Dysfunction in the sacroiliac joint (or SI joint) is thought to cause low back and/or leg pain. The leg pain can be particularly difficult, and may feel similar to sciatica or pain caused by a lumbar disc herniation.

Epidemiology and Need

Back pain is extremely common. 60-80% of people in the UK report back pain at some time in their lives. Low back pain has an estimated lifetime prevalence of 84% worldwide. The worldwide prevalence of chronic low back pain is about 23%. Simple back pain tends to affect those between 30 and 60 years of age, starting between 30 and 50. First onset outside this range should arouse suspicion of a sinister cause. Back pain is second only to the common cold as a cause of lost days at work. In 2005 the Trades Union Congress (TUC) estimated that 4.9 million working days per year are lost due to back pain. Research by the British Chiropractic Association found that 48% of people in Britain suffer from back or neck pain at any one time, possibly associated with spending an increasing amount of time

seated at office desks. Highly demanding jobs, prolonged standing and awkward lifting are the most consistent factors predisposing to low back pain. A systematic review did not identify occupational carrying as an independent risk factor. Psychosocial work-related stress is an associated factor. Genetics may play a part. Smoking and obesity increase risk.

Neck Pain The overall prevalence of neck pain in the general population ranges between 0.4% and 86.8% (mean: 23.1%); point prevalence ranges from 0.4% to 41.5% (mean: 14.4%); and 1 year prevalence ranges from 4.8% to 79.5% (mean: 25.8%). Prevalence is generally higher in women, higher in high-income countries compared with low- and middle-income countries and higher in urban areas compared with rural areas. Many environmental and personal factors influence the onset and course of neck pain. Most studies indicate a higher incidence of neck pain among women and an increased risk of developing neck pain until the 35-49-year age group, after which the risk begins to decline.

Sacroiliac joint (SIJ) pain is a source of mechanical low back pain, affecting between 15 and 30% of individuals with chronic, nonradicular pain. Predisposing factors for SIJ pain include true and apparent leg length discrepancy, older age, inflammatory arthritis, previous spine surgery, pregnancy and trauma. Compared with facet-mediated and discogenic low back pain, individuals with SIJ pain are more likely to report a specific inciting event, and experience unilateral pain below L5.

Adherence to NICE Guidance

This policy adheres fully to the recommendations made in NICE NG59.

Audit Requirements

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

Date of Review

Three 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
Anti-inflammatory	Used to reduce inflammation (a localized physical condition in which part of the body becomes reddened, swollen, hot, and often painful, especially as a reaction to injury or infection).
Chiropractic	A system of complementary medicine based on the diagnosis and manipulative treatment of misalignments of the joints, especially those of the spinal column.
Chronic	Persisting for a long time or constantly recurring.
Corticosteroid	Any of a group of steroid hormones produced in the adrenal cortex or made synthetically. There are two kinds: glucocorticoids and mineralocorticoids. They have various metabolic functions and some are used to treat inflammation.
Facet joints	The sliding joints allowing the vertebrae of the spine to glide over one another without losing contact

Fluoroscopic (x-ray)	An imaging technique that uses X-rays to obtain real-time moving images of the interior of an object.
Local anaesthetic	An anaesthetic that affects a restricted area of the body.
Musculoskeletal	Relating to or denoting the musculature and skeleton together.
NICE	National Institute for Health and Care Excellence
NICE CG	NICE Clinical Guidance
Psychosocial	Relating to the interrelation of social factors and individual thought and behaviour.
Spinal needle	A needle specially designed for used in spinal injections
Thoracic	The part of the body of a mammal between the neck and the abdomen, including the cavity enclosed by the ribs, breastbone, and dorsal vertebrae, and containing the chief organs of circulation and respiration; the chest
Vertebra	Each of the series of small bones forming the backbone, having several projections for articulation and muscle attachment, and a hole through which the spinal cord passes

References

- 1. Greater Manchester Effective Use of Resources Operational Policy
- 2. Patient + articles on Patient.co.uk on the epidemiology of back and neck pain
- 3. National Back Pain and Radicular Pain Pathway
- 4. NICE NG59: Low back Low back pain and sciatica in over 16s: assessment and management
- 5. NICE IPG578: Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain
- The epidemiology of neck pain. Hoy DG et al Best Pract Res Clin Rheumatol. 2010 Dec;24(6):783-92
- 7. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment. Cohen SP et al Expert Rev Neurother. 2013 Jan;13(1):99-116

Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	18/11/2015
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	12/07/2016
Greater Manchester Association Governing Group	19/07/2016
Bolton Clinical Commissioning Group	23/09/2016
Bury Clinical Commissioning Group	07/09/2016
Heywood, Middleton & Rochdale Clinical Commissioning Group	19/07/2016

Manchester Clinical Commissioning Group	Central: 01/11/2016 North: 26/08/2016 South: 01/11/2016	
Oldham Clinical Commissioning Group	19/07/2016	
Salford Clinical Commissioning Group	19/07/2016	
Stockport Clinical Commissioning Group	19/07/2016	
Tameside & Glossop Clinical Commissioning Group 03/08/201		
Trafford Clinical Commissioning Group 20/09/2016		
Wigan Borough Clinical Commissioning Group07/09/20		

Appendix 1 – Evidence Review

Facet Joint Injections for Neck and Back Pain GM070

Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. 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 NG59: Low back pain and sciatica in over 16s: assessment and management (Added at review: July 2017) - This guidance replaces CG88: Low back pain: Early management of persistent non-specific low back pain (also cited below)
Cochrane	Injection therapy for subacute and chronic low-back pain, Staal JB, de Bie R, de Vet HCW, Hildebrandt J, Nelemans P., <i>Cochrane Database of Systematic Reviews</i> 2008, Issue 3. Art. No.: CD001824.
York	Systematic review of diagnostic utility of facet (zygapophysial) joint injections in chronic spinal pain: an update Sehgal N, Dunbar EE, Shah RV, Colson J
BMJ Clinical Evidence	BMJ Clinical Evidence review: Low back pain (chronic): Facet Joint Injections, Roger Chou, Search date: April 2009
Other	Facet Joint Injection as a Diagnostic and Therapeutic Tool for Spinal Pain: A Review of Clinical and Cost Effectiveness, Canadian Agency for Drugs and Technology, Dianne Zakaria, PhD Becky Skidmore, BA(H), MLS March 2007
	GMSS Evidence Review - Cervical Facet Joint Injections - Feb 2017 (Added at review: July 2017)

Summary of the evidence

Thoracic facet joint injections

All of the evidence reviews felt that the level of evidence and consistency in findings was insufficient to show that facet joint injections for back pain were effective treatments. NICE NG59 recommends that this therapy is not routinely offered for back pain.

At the time of the July 2017 review no new systematic reviews of facet joint injections for back pain were identified. A further review was carried out for cervical facet joint injections and thoracic facet joint injections – very few papers related to thoracic facet joint injections and the evidence for this therapy was considered weak however for both neck and thoracic facet joint injections there was a subgroup of patients who appeared to get more benefit. The rapid appraisal previously carried out for neck pain has been incorporated into this this policy.

New NICE guidance on low back pain was published in November 2016, NG59: Low back pain and sciatica in over 16s: assessment and management, which replaces CG88: Low back pain in adults: early management. NICE guidance selection criteria for radiofrequency denervation (and therefore) for facet joint injections is slightly different so have been amended in this version, but the changes are not significantly different in what they commission.

Cervical Facet Joint Injections

NICE guidance and other systematic reviews highlighted the lack of evidence of effectiveness for this procedure for neck pain. In light of this evidence, facet joint injections for neck pain was considered to be an unproven therapy at the time the facet joint injections policy was developed and is not routinely commissioned. The reviews described the evidence as moderate or level 2. However, some of the cited studies were subject to several potential bias effects and the methodology was not always at the standard required by e.g. a Cochrane Review.

Summary

In summary, the evidence for therapeutic cervical joint injections suggests that this is still an unproven therapy. There are some benefits, but multiple injections into the same joint are required for medium term pain relief. One study suggested repeat injections as infrequently as 3 months apart. (NOTE: guidance for facet joint injections to the lumbar spine suggest a frequency of no more than 18 months apart). This treatment is unlikely to benefit the majority of patients with neck pain from facet joints however it may be beneficial for a select group of patients in the same way as therapeutic facet joint injections to the lumbar spine.

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 1: NICE GUIDANCE

CG88 Low back pain: Early management of persistent non-specific low back pain, May 2009, (This guidance has now been replaced by NICE NG59 - cited below)

RESEARCH RECOMMENDATIONS

4.5 Invasive procedures

What is the effectiveness and cost-effectiveness of facet joint injections and radiofrequency lesioning for people with persistent non-specific low back pain?

Why this is important

Many invasive procedures are performed on people with persistent non-specific low back pain. These are usually undertaken after the condition has lasted a long time (more than 12 months). Procedures such as facet joint injections and radiofrequency lesioning are performed regularly in specialist pain clinics. There is evidence that pain arising from the facet joints can be a cause of low back pain, but the role of specific therapeutic interventions remains unclear. Case studies provide some evidence for the effectiveness of facet joint injections and medial branch blocks, but randomised controlled trials give conflicting evidence.

Robust trials, including health economic evaluations, should be carried out to determine the effectiveness and cost effectiveness of invasive procedures – in particular, facet joint injections and radiofrequency lesioning. These should include the development of specific criteria for patient selection and a comparison with non-invasive therapies.

2. LEVEL N/A: NICE GUIDANCE

NICE NG59: Low back pain and sciatica in over 16s: assessment and management (This guidance replaces NICE CG88: Low back pain)

1.3 Invasive treatments for low back pain and sciatica

Non-surgical interventions

Spinal injections

1.3.1 Do not offer spinal injections for managing low back pain.

Radiofrequency denervation

- 1.3.2 Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when:
 - non-surgical treatment has not worked for them and
 - the main source of pain is thought to come from structures supplied by the medial branch nerve **and**
 - they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral.
- 1.3.3 Only perform radiofrequency denervation in people with chronic low back pain after a positive response to a diagnostic medial branch block.
- 1.3.4 Do not offer imaging for people with low back pain with specific facet join pain as a prerequisite for radiofrequency denervation.

Epidurals

- 1.3.5 Consider epidural injections of local anaesthetic and steroid in people with acute and severe sciatica.
- 1.3.6 Do not use epidural injections for neurogenic claudication in people who have central spinal canal stenosis.

3. LEVEL 1: SYSTEMATIC REVIEW

Facet Joint Injection as a Diagnostic and Therapeutic Tool for Spinal Pain: A Review of Clinical and Cost Effectiveness, Canadian Agency for Drugs and Technology, Dianne Zakaria, PhD Becky Skidmore, BA(H), MLS March 2007

Conclusions and Implications for Research and Policy

Ideally, all health care practices should be evidence-based. Because FJIs are costly, invasive procedures with associated risks and xray exposure, the importance of this requisite is magnified. According to the RCTs completed to date, FJIs with local anaesthetics or steroids have not been proven to be superior to placebo for the treatment of chronic LBP. Steroid FJIs have not been proven to be superior to local anaesthetic FJIs in the treatment of chronic neck pain secondary to a motor vehicle accident. The studies are limited. The most common limitation was the lack of appropriate diagnostic procedures to identify patients with pain of FJ origin. Only Barnsley *et al.*17 executed comparative-controlled FJ medial nerve branch blocks to identify an appropriate patient group before randomization. Future RCTs should:

- execute appropriate diagnostic procedures to identify patients with pain of FJ origin before randomization
- include adequate sample sizes based on a priori sample size calculations
- use a standardized treatment, with information about any concurrent treatment clearly stated
- establish the efficacy of FJIs relative to placebo before comparing medications with each other
- have an adequate follow-up duration of at least 12 months to ascertain long-term effects
- acknowledge basic study quality criteria such as concealment of allocation, baseline comparability of groups, blinding, documentation of loss to follow-up, and intention to treat analysis
- include economic evaluations to provide needed information about the costs of observed effects relative to alternative interventions.

Although FJIs have not been proven to be efficacious for the treatment of chronic LBP or chronic neck pain secondary to a motor vehicle accident, placebo- or comparative-controlled FJIs or medial nerve branch blocks are the standard for diagnosing pain of FJ origin. Unequivocally effective treatments with long term impacts remain elusive. In the meantime, guidelines have been developed for more judicious therapeutic use of FJIs on a case by case basis. It has been recommended that FJIs be used to facilitate other forms of active conservative treatment, such as physical exercise, rather than as a stand-alone pain treatment Although Mayer *et al.* did not find FJIs with local anaesthetics and steroids to be an effective addition to exercise alone, the study groups did not consist of patients with confirmed pain of FJ origin. Using bone scintigraphy with SPECT to identify appropriate patients and target FJIs may offer a less burdensome and more cost-effective approach to management. More research is needed to evaluate this technology.

4. LEVEL 1: SYSTEMATIC REVIEW

Injection therapy for subacute and chronic low-back pain, Staal JB, de Bie R, de Vet HCW, Hildebrandt J, Nelemans P., *Cochrane Database of Systematic Reviews* 2008, Issue 3. Art. No.: CD001824.

ABSTRACT

Background: The effectiveness of injection therapy for low-back pain is still debatable. Heterogeneity of target tissue, pharmacological agent and dosage generally found in randomized controlled trials (RCTs) points to the need for clinically valid comparisons in a literature synthesis.

Objectives: To determine if injection therapy is more effective than placebo or other treatments for patients with subacute or chronic low-back pain.

Search methods: We updated the search of the earlier systematic review and searched the Cochrane Central Register of Controlled Trials, MEDLINE and EMBASE databases from January 1999 to March 2007 for relevant trials reported in English, French, German, Dutch and Nordic languages. We also screened references from trials identified.

Selection criteria: RCTs on the effects of injection therapy involving epidural, facet or local sites for subacute or chronic low-back pain were included. Studies which compared the effects of intradiscal injections, prolotherapy or Ozone therapy with other treatments, were excluded unless injection therapy with another pharmaceutical agent (no placebo treatment) was part of one of the treatment arms. Studies about injections in sacroiliac joints and studies evaluating the effects of epidural steroids for radicular pain were also excluded.

Data collection and analysis: Two review authors independently assessed the quality of the trials. If study data were clinically and statistically too heterogeneous to perform a meta-analysis, we used a best evidence synthesis to summarize the results. The evidence was classified into five levels (strong, moderate, limited, conflicting or no evidence), taking into account the methodological quality of the studies.

Main results: 18 trials (1179 participants) were included in this updated review. The injection sites varied from epidural sites and facet joints (i.e. intra-articular injections, peri-articular injections and nerve blocks) to local sites (i.e. tender- and trigger points). The drugs that were studied consisted of corticosteroids, local anesthetics and a variety of other drugs. The methodological quality of the trials was limited with 10 out of 18 trials rated as having a high methodological quality. Statistical pooling was not possible due to clinical heterogeneity in the trials. Overall, the results indicated that there is no strong evidence for or against the use of any type of injection therapy.

Authors' conclusions: There is insufficient evidence to support the use of injection therapy in subacute and chronic low-back pain. However, it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy.

5. LEVEL N/A: WEB GUIDANCE

BMJ Clinical Evidence review: Low back pain (chronic): Facet Joint Injections, Roger Chou, Search date: April 2009

SUMMARY STATEMENT

Symptom improvement

Facet joint injections compared with placebo. We don't know whether facet joint injections are more effective at decreasing pain in people with chronic low back pain (30Tvery low-quality evidence30T).

Functional improvement

<u>Corticosteroid injections compared with saline injections</u>. We don't know whether corticosteroid injections are more effective at improving disability at 1 and 3 months in people with chronic low back pain (very low-quality evidence).

BENEFITS

Facet joint injection versus placebo:

We found two systematic reviews (search dates 2008 and 2007). The reviews both reported the same two RCTs, neither review pooled data owing to heterogeneity between trials, and both reported that the first RCT is of high quality, and the second RCT is of low quality.

The first RCT included in both reviews (101 people with chronic low back pain without sciatica, with positive response to an uncontrolled facet joint block, see comment below) found no significant difference in pain relief and disability between corticosteroid and saline injections after 1 and 3 months (1 month: RR 0.89, 95% CI 0.65 to 1.21; 3 months: RR 0.90, 95% CI 0.69 to 1.17). Although a significantly higher proportion of people in the corticosteroid-injection group experienced marked or very marked improvement in pain relief after 6 months (46% with corticosteroid v 15% with placebo; P = 0.002), half of the people in the corticosteroid-injection group with positive results at 6 months experienced no benefits at earlier time periods, and differences were attenuated after controlling for increased use of co-interventions in the corticosteroid-injection group.

The second RCT included in both reviews (109 people with chronic low back pain based on clinical criteria, positive response to diagnostic facet joint block not required, see comment below) compared corticosteroids injected intra-articularly versus corticosteroids injected peri-capsularly versus placebo injections. No significant differences were reported between the groups for pain, disability, and work attendance at 1 hour, 2 weeks, 6 weeks, and 3 months (reported as not significant; P value not reported).

HARMS: The reviews reported that adverse effects such as headache, dizziness, transient local pain, tingling and numbress, and nausea were reported in small numbers of people (no further data reported).

COMMENT: Two other RCTs identified by the review did not distinguish between acute and chronic pain, and involved people with sciatica, so these RCTs have not been included here. The RCTs included in both reviews included people with pain arising from the facet joints. This is likely to indicate a definitive diagnosis for the source of low back pain.

6. LEVEL N/A: POOR QUALITY SYSTEMATIC REVIEW

Systematic review of diagnostic utility of facet (zygapophysial) joint injections in chronic spinal pain: an update, Sehgal N, Dunbar EE, Shah RV, Colson J

CRD summary: This review concluded that local anaesthetic blocks of facet joints were reproducible, accurate and safe. The results presented did not appear to provide data on the reproducibility of facet joint blocks and the only data provided on accuracy related to false-positive rates, which seemed very high. The conclusions are therefore not supported by the data presented.

Authors' objectives: To evaluate the utility of facet joint block injections for the diagnosis of chronic spinal pain.

Searching: PubMed, EMBASE and CINAHL were searched from October 2004 to December 2006. In addition, the references of systematic and narrative reviews were screened for additional studies. The search terms were reported. The studies identified by these update searches were added to those identified by the previous review, which had been published in 2005 (see Other Publications of Related Interest).

STUDY SELECTION

Study designs of evaluations included in the review: Prospective and retrospective studies were eligible for inclusion. Case reports and reviews were excluded. The included studies were randomised controlled trials and prospective and retrospective studies.

Specific interventions included in the review: Studies that assessed diagnostic facet joint procedures that involved fluoroscopically/image-guided injections and controlled for false-positive responses (used comparative control or placebo control blocks) were eligible for inclusion. Studies that described injection techniques or ultrasound-guided infections were excluded, as were papers on therapeutic facet joint procedures.

Reference standard test against which the new test was compared: The reference standard for the diagnosis of zygapophysial facet joint pain was at least 50% pain relief for duration of the anaesthetic effect.

Participants included in the review: Studies of patients with spinal pain of greater than 3 months' duration were eligible for inclusion. Anatomical/cadaver studies were excluded.

Outcomes assessed in the review: No inclusion criteria relating to the outcomes were reported. The outcomes reported in the review were the prevalence of facet joint pain as a source of chronic spinal pain and false-positive rates.

How were decisions on the relevance of primary studies made? The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality: Two clinical reviewers assessed the studies for methodological quality using the AHRQ (Agency for Healthcare Research and Quality) criteria for diagnostic studies and the QUADAS (Quality Assessment of Diagnostic Accuracy Studies) criteria. Studies had to fulfil at least 3 of the 5 AHRQ criteria and 7 of the 14 QUADAS criteria to be included in the review. The results of the quality assessment were reported as scores.

Data extraction: The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

METHODS OF SYNTHESIS

How were the studies combined? There were no details of the methods used to synthesise the results and a narrative synthesis was presented. The results of the individual studies were summarised.

How were differences between studies investigated? Differences between the studies were not formally investigated. The results of the individual studies were grouped according to region of the back assessed.

Results of the review: Two studies were identified by the current searches. These were added to the 37 studies identified for the previous review, giving a total of 39 included studies (total number of participants unclear). Cervical region (8 studies, 1,002 patients). Prevalence of facet joint pain was reported in 7 studies and ranged from 36 to 67%. The false-positive rate, which was reported in 5 studies, ranged from 27 to 63%. AHRQ scores ranged from 3 to 4 out of 5; QUADAS scores ranged from 7 to 13 out of 14. Thoracic region (3 studies, 183 patients). Prevalence of facet joint pain ranged from 34 to 48%. The false-positive rate ranged from 42 to 58%. All studies scored 3 out of 5 on the AHRQ criteria; QUADAS scores ranged from 14 to 52%. The false-positive rate, which was reported in 13 studies, ranged from 17 to 50%. AHRQ scores ranged from 3 to 4 out of 5 and 1 study appeared to score 1 out of 4; QUADAS scores ranged from 7 to 12 out of 14. One study reported a case of transient paraplegia after a cervical facet joint injection. Another reported a vasovagal episode and a short duration procedure-related discomfort. Seven other studies reported other complications with infection and bleeding.

Authors' conclusions: Controlled, comparative, local anaesthetic blocks of facet joints are reproducible, accurate and safe.

CRD commentary: This review addressed a focused question that was supported by defined inclusion criteria. The literature search was limited to three databases over a 2-year period but, given that this was an update of a previous review, the date restrictions were appropriate. No attempts were made to locate unpublished studies so the review may be subject to publication bias. A detailed quality assessment was conducted, but the results of this were expressed as summary quality scores with no discussion of the individual quality items. The validity of the primary studies therefore remains unclear. Some details of a sample of the included studies were reported in the tables, but these did not provide sufficient information on the primary studies for the reader to judge their similarity and clinical relevance, and for some studies no details were provided; this makes it very difficult to interpret the results of the review. A narrative synthesis was presented but this was confusing and did not appear to address all of the

included studies. Given the types of studies included it might have been more appropriate to conduct some form of statistical analysis; however, given the very limited details provided on the included studies it is difficult to assess this. The results presented did not appear to provide data on the reproducibility of facet joint blocks and the only data provided on accuracy related to false positive rates, which appeared very high. The authors' conclusions are therefore not supported by the data presented, and the lack of data relating to the included studies makes the results of the review almost impossible to interpret.

7. LEVEL N/A: RAPID APPRAISAL GMSS Evidence Review - Cervical Facet Joint Injections - Feb 2017

Available on request.

Appendix 2 – Post Consultation additional Evidence Review Summary Table

Facet Joint Injections for Neck and Back Pain GM070

See link: Post Consultation additional Evidence Review Summary Table

Appendix 3 – Diagnostic and Procedure Codes

Facet Joint Injections for Neck and Back Pain GM070

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

GM070 - Facet Joint Injections for Back Pain		
Injection around spinal facet of spine	V54.4	
Approach to organ under fluoroscopic control	Y53.4	
With the following ICD-10 diagnosis code(s):		
Panniculitis affecting regions of neck and back	M54.0	
Radiculopathy	M54.1	
Cervicalgia	M54.2	
Sciatica	M54.3	
Lumbago with sciatica	M54.4	
Low back pain	M54.5	
Pain in thoracic spine	M54.6	
Other dorsalgia	M54.8	
Dorsalgia, unspecified	M54.9	
Exceptions (ICD-10):		
Personal history of long-term (current) use of anticoagulants		
Comorbidities – this is too broad a description as could cover a multitude of codes		

Appendix 4 – Version History

Facet Joint Injections for Neck and Back Pain GM070

The latest version of this policy can be found here: <u>GM Facet Joint Injections for Back Pain policy</u>

Version	Date	Summary of Changes
0.1	06/03/2015	Initial draft
		 Initial draft On the 16th September 2015 the Greater Manchester EUR Steering Group agreed the following changes to the policy:- Under Section 4 Criteria for Commissioning the 'Mandatory Criteria' was amended to read as follows:- 'Current Patients Facet Joint injections will continue to be commissioned for existing patients provided that there is a demonstrable improvement in quality of life measures following each treatment, this should be assessed using a validated research tool. Treatments should only continue where alternative treatments such as analgesic medication are intolerable or produce undesirable side effects, such as unsteadiness in the elderly. If treatment with facet joint injections are successful on more than two occasions suitable individuals should be referred for radiofrequency denervation if facet joint injections are to continue then the individual should be considered unsuitable for radiofrequency denervation including but not limited to: The presence of comorbidities that contraindicate radiofrequency denervation Access or other anticipated mechanical difficulties in the delivery of radiofrequency denervation Inability of the patient to adopt or maintain the required position for the safe delivery of radiofrequency denervation Thare is limited to no more than 2 injections a year the interval between injections should be at least 6 months but ideally be no more frequent than 8-12 month intervals. Facet joint injections should <u>not</u> be administered if: There patient is receiving substantial therapeutic or constitutional anticoagulation The patient is nowilling or is demonstrating a lack of cooperation <u>Diagnostic Injections are commissioned on monitored approval for patients being assessed for radiofrequency denervation in line with the radiofrequency denervation policy only any other diagnostic use of facet joint</u>
		injections will require an Individual Funding Request application. <u>New Patients</u> Facet joint injections are commissioned for patients who meet the following criteria:
		 The back pain has been present for more than 1 year and all chronic pain management pathways have failed. AND
		 There is no other treatment option available for the patient OR
		• Alternative treatments such as analgesic medication are intolerable or

		produce undesirable side effects OR
		 The patient has demonstrated failure to respond to, or had a loss of response to other treatment options OR
		 Other treatment options are contraindicated and this is clearly documented Wherever possible patients should be encouraged to: participate in mobilisation or rehabilitation therapy take effective pain relief medication where indicated (and where it is available) be referred for weight
		• where indicated (and where it is available) be referred for weight management support'
1.0	18/11/2015	 On the 18th November 2015 the GM EUR Steering Group approved the changes made to the policy on the 16th September 2015 and requested the following additional changes be made:- The order of the <u>Mandatory Commissioning</u> Criteria be changed to:- New patients Diagnostic injections Current patients With the following sentence being added under new patients:- 'If new patients gain relief from facet joint injections and are suitable for radiofrequency denervation and have a positive response to facet joint injections they should be referred for radiofrequency denervation.' The wording in Diagnostic Injections amended to read as follows:- 'Facet joint injections are commissioned on Individual Prior Approval for patients being assessed for radiofrequency denervation in line with the Radiofrequency Denervation Policy only, any other diagnostic use of facet joint injections will require an Individual Funding Request application. Patients given prior approval for two diagnostic injections will be considered to have prior approval for radiofrequency denervation fit he response to both injections is positive' With the following sentence being added for current patients: 'All patients who are suitable for radiofrequency denervation should be referred after two successful facet joint injections.' Funding Mechanism updated to read as follows:- 'New patients – funding will be by individual prior approval (IPA) for 2 injections per year for patients meeting the mandatory criteria. Funding for other patients may be considered on an individual patient basis, if there is evidence of clinically exceptional circumstances. Diagnostic facet joint injections - Facet joint injections are commissioned on Individual Prior Approval (IPA) for patients being assessed for radiofrequency denervation in line with the Radiofrequency Denervation Policy only. Any other diagnostic use of facet joint injections are optissioned on I
		Subject to the above changes being made the GM EUR Steering Group approved the policy to be sent to through the governance process.
	15/03/2016	Report updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater

	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)" on 'Policy Statement' and section '13. Date of Review'.
1.1 19/07/2016 I	Diagnostic and Procedure Codes added as Appendix 3
	 Section 4 - Mandatory Criteria Under 'Current Patients' the GM EUR Steering Group agreed to add the following sentence to the final paragraph '<u>OR</u> where the diagnosis is clear and a single facet joint injection supports the diagnosis, patients may be referred following one injection.' Typographical error corrected in 'Funding Mechanism' and 'Mandatory Criteria - Diagnostic Injections' from "two diagnostic injections will be conserved to have" to read "two diagnostic injections will be considered to have"
	Following GM EUR Steering Group on 16/11/2016 references to neck pain were removed from policy (including the name) where appropriate.
	 Following scheduled review at GM EUR Steering Group on 19 July 2017 the following amendments were agreed: Policy updated to new format. Title of policy amended to: '<i>Facet Joint Injections for Neck and Back Pain</i>' Policy Inclusion Criteria Title sadded to each of the sections and parts reworded for clarity Bullet points added under 'New Patients: Lumbar' to state: 'the main source of pain is thought to come from structures supplied by the medial branch nerve AND they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral.' Second bullet point moved to fourth and the following added: '(i.e. non-surgical treatment has not worked for them)' New sections added for 'New Patients: Thoracic', 'New Patients: Cervical' and 'New Patients: Sacrolliac' 'Diagnostic Facet Joint Injections' section re-worded for clarity. Treatment/Procedure: Second paragraph updated due to review and two paragraphs added on neck pain and sacrolliac joint pain. Epidemiology and Need: Two paragraphs added on neck pain and sacrolliac joint pain. Epidemiology and Need: Two paragraphs added on neck pain and sacrolliac joint pain. Adherence to NICE Guidance: Amended to read: 'This policy adheres fully to the recommendations made in NICE NG59.' Date of Review: Section amended to state: 'Three years from the date of the last review, unless new evidence is available sooner'. References: Five further references added Appendix 1 - Evidence Review: NICE CG88 citation updated to NG59 and one citation added to 'Search Strategy' table and a summary added to 'The Evidence'. Paragraph added to 'Summary of the evidence' summarising what was found in July 2017 review search and including cervical facet joint injections.
2.1 21/11/2018	The GM EUR Steering Group agreed the following amendments:

		 <u>Commissioning Statement:</u> Best Practice Guidelines section added <i>'New Patients: Sacroiliac'</i> section renamed to <i>'Sacroiliac joint pain'</i>. The section rewritten and funding mechanism amended. The above changes were not considered to be material and therefore it was not necessary for the amended policy to go back through the governance process again. Branding also changed to reflect change of service from Greater Manchester Shared Services to Greater Manchester Health and Care Commissioning.
2.2	25/01/2019	 Links updated as documents have all moved to a new EUR web address. <u>Commissioning Statement:</u> 'Best Practice Guideline' section moved to bottom of 'Commissioning Statement'