

London Choosing Wisely

Draft Policy Template:

Interventional treatments for back pain

Version	Date	Notes
Draft for Task & Finish Group 1	17/04/18	Initial draft
Revised version post Task & Finish Group 1	04/05/18	Criteria for commissioning Rationale for commissioning completed Adherence to NICE guidance completed Governance statement completed Updated ICD-10 and OPCS codes Summary of findings – spinal cord stimulation amended Additional evidence for ozone discectomy and sacroiliac joints reviewed Ozone discectomy specifically added to commissioning criteria
Revised version post Task & Finish Group 2	17/05/18	Commissioning criteria updated Epidural lysis specifically added to commissioning criteria Advice for primary care updated Appendix 2 updated to include LCW policy
Revised version following T&F Chair's final amendments	04/06/18	Epidural lysis commissioning criteria updated.
Revised version following chair's review of comments from "sense check"	27/06/18	Explanatory text added in several places, in response to feedback from "sense check". Spinal cord stimulation criterion removed (new technology appraisal is expected this autumn).
Revised following further chair's review of feedback	12/07/18	Specific proposed timescale for one intervention revised
Revised following LCW Steering Group	20/08/18	Text added to search strategy section of evidence review appendix following discussion at July Steering group meeting
Final	18/10/18	Inconsistent wording removed

COMMISSIONING STATEMENT

Intervention	Interventional treatments for back pain
Date Issued	
Dates of Review	
Pan-London Commissioning Recommendation	<p>This policy relates to interventional treatments for back pain only, as described in detail below. For many patients, consideration of such treatments only arises after conservative management in primary care or specialist musculoskeletal services.</p> <p>The following exclusions apply:</p> <ul style="list-style-type: none"> • Children. • Patients thought to have/have cancer (including metastatic spinal cord compression). • Patients with neurological deficit (spinal cord compression or cauda equina symptoms), fracture or infection. <p>In ordinary circumstances, funding for interventional treatments for back pain is available for patients who meet the following criteria.</p> <p>If the clinician considers the need for treatment on clinical grounds outside of these criteria, please refer to the CCG's Individual Funding Request policy for further information.</p> <p>This policy relates to adults over 16 years.</p> <p><u>Epidurals</u></p> <p>The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement AND The patient has moderate-severe symptoms that have persisted for 12 weeks or more (earlier if there are motor symptoms or there is no access to MRI) AND The patient has shown no sign of improvement despite conventional therapy of advice, reassurance, analgesia and manual therapy AND/OR The MRI scan (unless contraindicated) shows pathology concordant with the clinical diagnosis. A maximum of 3 epidural injections will be permitted, with evidence based on the following response rates:</p> <ul style="list-style-type: none"> • 30% improvement after the first injection • 50% improvement after the second injection <p>For patients with persisting symptoms after 3 injections, re-</p>

approval of treatment with epidural injections will be needed through the IFR panel. This may be older/frailer patients who derive medium term benefit but are unsuitable or unwilling to have surgery.

Spinal decompression

The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement

AND

The MRI scan (unless contraindicated) shows one or more areas of spinal stenosis whereby the pathology is concordant with the clinical diagnosis.

AND

The patient has shown no sign of improvement despite conventional therapy for 1 year.

Discectomy

The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement

AND

The patient has shown no sign of improvement despite conventional therapy for 12 weeks

AND

Patients have acute, severe and unremitting sciatica concordant with disc herniation demonstrated on MRI scan within 12 weeks (unless contraindicated).

Radiofrequency Denervation (including non-anterior radicular cervical, thoracic and lumbar areas)

Patient has persistent pain

AND

Conservative management including physiotherapy and multidisciplinary input has failed to achieve meaningful relief of pain

AND

MRI or SPECT (unless contraindicated) findings are concordant with the patient's symptoms and other structural lesions are excluded

AND

The patient has had an 80% improvement in pain from a diagnostic medial branch block, which is clearly documented in the patient's notes.

For each affected nerve level, the patient should have one diagnostic medial branch block followed by one therapeutic radiofrequency denervation procedure. If further treatment is required through radiofrequency denervation, approval should be sought through the IFR panel.

Diagnostic Spinal injections (including facet joint injections, medial branch blocks and sacroiliac joint injections)

Patient is under the care of a specialist

The patient may have up to two diagnostic spinal injections (if

	<p>both short and long acting injections are being used) within a two-week period. The second diagnostic spinal injection may only be given if the first elicits 80% improvement in pain and this is clearly documented in the notes.</p> <p><u>Epidural Lysis (See also NICE IPG 333)</u> The patient has late onset radiculopathy post spinal surgery AND MRI Gadolinium Enhanced or dynamic epidurogram (unless contraindicated) findings are concordant to show adhesive radiculopathy AND Conservative management, manipulation therapy, epidural injections or transforaminal injections (where funding was prior approved) has failed.</p> <p>The specialist applying for funding must confirm that they are trained in the technique.</p> <p>This treatment will only be funded once. Subsequent epidural lysis treatments will require an IFR referral, including information about the nature and duration of benefit from initial treatment.</p> <p><u>Therapeutic Spinal injections (including facet joint injections, medical branch blocks, intradiscal therapy, prolotherapy, trigger point injections, sacroiliac joint injections)</u> Spinal injections are not routinely funded.</p> <p><u>Spinal Fusion</u> Spinal fusion surgery is not routinely funded for non-radicular back pain.</p> <p><u>Lumbar Disc Replacement</u> Lumbar disc replacement surgery is not routinely funded.</p> <p><u>Acupuncture</u> Acupuncture for back pain is not routinely funded.</p> <p><u>Ozone Discectomy</u> Ozone discectomy is not routinely funded.</p>	
Prepared By	London Choosing Wisely, Commissioned by NHSE	
Approved By	Date Approved	Notes
Interventional treatments for back pain Task & Finish Group, London Choosing Wisely	13/07/2018	

LCW Steering Board	04/09/2018	
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Main Policy Document

Policy Statement

London Choosing Wisely (LCW) was commissioned to carry out this work on behalf of all London Clinical Commissioning Groups (CCGs), in order to promote equitable access to certain treatments and the cost-effective use of healthcare resources. All London CCGs will commission the interventional treatments for back pain in accordance with the criteria outlined in this document.

In creating this policy, LCW convened a task and finish group focused on developing this policy and has reviewed this clinical condition and the evidence supporting treatment leading to this commissioning decision.

1. Introduction

Back pain is very common, especially as a presentation to General Practice, and usually self-limiting. It is also important to recognise that 'back pain' itself has a wide-ranging definition, covering a number of different diagnoses. There is a smaller proportion of patients within this with 'red flag' symptoms, who may need different management, including specialist opinion, diagnostic tests or further treatment.

Currently much health service resource is utilised to provide very little positive benefit for patients. However, it can lead to considerable disability, in part through well-intentioned over-medicalisation of initial care management.

The condition has a huge cost to the individual, society and the country's economy. Therefore, it is important to review up to date existing guidance relating to interventional treatments for back pain in order to inform later development of policy. Ultimately, this can help to ensure the right care can be provided for the right patient at the right time.

This policy is intended to apply to patients with recent onset of pain as well as those for whom back pain has become established.

The majority of evidence reviewed to inform development of this policy related to lumbar back pain and associated radiculopathy. However, other aspects of spinal pain have been included where possible.

2. Key Definitions

- Epidurals: injections into the epidural space, includes interlaminar, transforaminal, caudal approaches.
- Spinal injections: includes facet joint injections, medial branch blocks, intradiscal therapy, prolotherapy, trigger point injections.
- Spinal fusion: operation performed to achieve solid bone union between spinal vertebrae to prevent movement. Involves using patient's own bone or artificial bone substitutes. It is commonly carried out as a component part of many types of spinal operation; operations to correct deformity remove tumours and treat spinal fractures. In clinical practice, spinal fusion is sometimes used to treat severe and constant low back pain that has not resolved with more conservative treatments.
- Spinal decompression: Spinal decompression refers to removal of pressure from the nervous structures within the spinal column. An example would be laminectomy, which may also include foraminotomy/trimming of overgrown facets and or

discectomy. Most common cause of spinal canal narrowing is degenerative lumbar disease, otherwise known as spondylosis. Associated symptoms are neurogenic claudication (pain and/or numbness/weakness worse with prolonged standing). Disc prolapse, on the other hand, causes leg pain and sciatica.

- Sacro-iliac joint injection: primarily used to either diagnose or treat low back pain and / or sciatica associated with sacroiliac dysfunction. Also called a sacroiliac joint block,
- Radiofrequency denervation: Radiofrequency facet denervation is a minimally invasive procedure used to treat back pain caused by arthritis or injury to the facet joints. This procedure is also called RFD, radiofrequency neurotomy or radiofrequency rhizotomy.
- Epidural lysis: a minimally invasive form of surgery used to treat people with low back and leg pain caused by epidural adhesions (type of scar tissue in the spine). An endoscope is inserted into the epidural space under fluoroscopic guidance, and used to identify and separate affected nerve roots from scar tissue.
- Disc replacement: Procedure involves replacing intervertebral units with artificial discs that can act as a functional prosthetic replacement. Pain relief stems from removal of the painful disc. Single/multiple discs can be replaced during the same surgery. Some clinicians consider the advantage of disc arthroplasty over spinal fusion is that it preserves movement.
- Acupuncture: complementary medicine in which fine needles are inserted into the skin at specific points along lines of energy (meridians).

3. Aims & Objectives

- To reduce unwarranted variation in access of interventional treatments for back pain.
- To ensure that the interventional treatments for back pain is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness
- To promote the cost-effective use of healthcare resources

4. Criteria for commissioning

Advice for Primary Care Practitioners

Low back pain is a very common presentation, especially to General Practice. It is a soreness or stiffness in the back, between the bottom of the rib cage and the top of the legs. Most people's low back pain is described as 'non-specific'. Some people also get back symptoms radiating down one or both legs (radicular symptoms/sciatica). Radicular symptoms are caused, when the nerves from the back, are irritated causing pain, numbness or tingling down the leg.

This pain is usually self-limiting and the majority of patients will find their symptoms resolve without treatment or with conservative management. Conservative management may include reassurance, advice and guidance with a holistic assessment (where tools such as STarT Back can be helpful) and/or simple analgesia with safety netting. Patients with "red flag" pathologies should be treated on alternative pathways.

The commissioning criteria set out in this document should not delay referral for assessment of patients with uncontrollable pain despite conventional treatment.

However, whilst primary care is not directly responsible for requesting prior approval, primary care practitioners must be aware of the detailed clinical criteria relating to this commissioning policy before referring the patient to the appropriate service.

Primary care practitioners must also ensure that patients have engaged in shared decision making for potential further intervention and that they supply all the relevant information to secondary care, particularly concerning conservative treatments.

Primary care should ensure that, where appropriate, the patient has meaningfully engaged with conservative management. These include education and lifestyle modifications, exercise and physiotherapy. Primary care practitioners should encourage smoking cessation and weight reduction (where appropriate), offering referral to appropriate services, where required. These lifestyle changes have the potential to improve general health and wellbeing, as well as, intervention success rates and enhance recovery times from surgery.

The following exclusions apply:

- Children.
- Patients thought to have/have cancer (including metastatic spinal cord compression).
- Patients with neurological deficit (spinal cord compression or cauda equina symptoms), fracture or infection.

In ordinary circumstances, funding for interventional treatments for back pain is available for patients who meet the following criteria:

If the clinician considers the need for treatment on clinical grounds outside of these criteria, please refer to the CCG's Individual Funding Request policy for further information.

This policy relates to adults over 16 years.

For many patients, consideration of such treatments only arises after conservative management in primary care or specialist musculoskeletal services

Epidurals

The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement

AND

The patient has moderate-severe symptoms that have persisted for 12 weeks or more (earlier if there are motor symptoms or there is no access to MRI)

AND

The patient has shown no sign of improvement despite conventional therapy of advice, reassurance, analgesia and manual therapy

AND/OR

The MRI scan (unless contraindicated) shows pathology concordant with the clinical diagnosis.

A maximum of 3 epidural injections will be permitted, with evidence based on the following response rates:

- 30% improvement after the first injection
- 50% improvement after the second injection

For patients with persisting symptoms after 3 injections, re-approval of treatment with epidural injections will be needed through the IFR panel. This may be older/frailer patients who derive medium term benefit but are unsuitable or unwilling to have surgery.

Spinal decompression

The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement

AND

The MRI scan (unless contraindicated) shows one or more areas of spinal stenosis whereby the pathology is concordant with the clinical diagnosis.

AND

The patient has shown no sign of improvement despite conventional therapy for 1 year.

Discectomy

The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement

AND

The patient has shown no sign of improvement despite conventional therapy for 12 weeks

AND

Patients have acute, severe and unremitting sciatica concordant with disc herniation demonstrated on MRI scan within 12 weeks (unless contraindicated).

Radiofrequency Denervation (including non-anterior radicular cervical, thoracic and lumbar areas)

Patient has persistent pain

AND

Conservative management including physiotherapy and multidisciplinary input has failed to achieve meaningful relief of pain

AND

MRI or SPECT (unless contraindicated) findings are concordant with the patient's symptoms and other structural lesions are excluded

AND

The patient has had an 80% improvement in pain from a diagnostic medial branch block, which is clearly documented in the patient's notes.

For each affected nerve level, the patient should have one diagnostic medial branch block followed by one therapeutic radiofrequency denervation procedure. If further

treatment is required through radiofrequency denervation, approval should be sought through the IFR panel.

Diagnostic Spinal injections (including facet joint injections, medial branch blocks and sacroiliac joint injections)

Patient is under the care of a specialist

The patient may have up to two diagnostic spinal injections (if both short and long acting injections are being used) within a two-week period. The second diagnostic spinal injection may only be given if the first elicits 80% improvement in pain and this is clearly documented in the notes.

Epidural Lysis (See also NICE IPG 333)

The patient has late onset radiculopathy post spinal surgery
AND

MRI Gadolinium Enhanced or dynamic epidurogram (unless contraindicated) findings are concordant to show adhesive radiculopathy

AND

Conservative management, manipulation therapy, epidural injections or transforaminal injections (where funding was prior approved) has failed.

The specialist applying for funding must confirm that they are trained in the technique.

This treatment will only be funded once. Subsequent epidural lysis treatments will require an IFR referral, including information about the nature and duration of benefit from initial treatment.

Therapeutic Spinal injections (including facet joint injections, medial branch blocks, intradiscal therapy, prolotherapy, trigger point injections, sacroiliac joint injections)

Spinal injections are not routinely funded.

Spinal Fusion

Spinal fusion surgery is not routinely funded for non-radicular back pain.

Lumbar Disc Replacement

Lumbar disc replacement surgery is not routinely funded.

Acupuncture

Acupuncture for back pain is not routinely funded.

Ozone Discectomy

Ozone discectomy is not routinely funded.

5. Evidence Summary

The full evidence review can be found in Appendix 1, and a shorter summary of findings has been included.

Epidural adhesions and epidural lysis was not part of the original evidence search, but relevant papers were brought to the notice of the Group by one of the members, and the commissioning criterion was based on these and best available clinical opinion.

6. Rationale behind Policy Statements

In drafting this commissioning policy, the Task and Finish Group considered the evidence presented, the current position of CCGs within London, and their clinical experience. Furthermore, they recognised that there is currently variation in service provision for low back pain across London.

The Task and Finish Group noted that “radicular pain” and “low back pain” were separate conditions. However, agreed that pathology in the back is common to both conditions; that they may share similar causation, and thus they should be covered in one single pan London policy.

Further, this aligned with the NHSE National Back Pain Pathway, where the diagnoses are covered in a single policy incorporating two pathways.

The Task & Finish Group noted that there are occasional circumstances in which a procedure or intervention for low back pain is clinically indicated and these circumstances are listed in this policy.

Inclusion/Exclusion: The Task and Finish Group concluded that patients with malignancy or suspected malignancy, signs or symptoms of neurological deficit (spinal cord compression or cauda equina), fracture or infection are excluded from this policy.

Criteria for commissioning: The Task and Finish Group noted the difficulty in prescribing specific, evidence based criteria for when a patient should undergo intervention. There will always be a subjective definition of *moderate* or *severe* pain and so clinicians will need to apply reason to this judgement, understanding that it is the responsibility of all clinicians to use resources appropriately.

7. Adherence to NICE Guidelines

The Task & Finish group noted that there were recent NICE guidelines with a robust global evidence base underpinning them. Therefore, the NICE guidelines were compared to the more recent NHSE guidance and Lancet review to form the final policy:

- NICE guidance (*Low back pain and sciatica in over 16s: assessment and management invasive treatments*, Nov. '16)
- Lancet paper (*Low back pain 2: Prevention and treatment of low back pain: evidence, challenges, and promising directions*, Mar. '18)
- NHSE National Low Back and Radicular Pain Pathway 2017.

8. Codes for procedures

As there are a large number of possible codes, these have been included as an appendix to this policy.

Equality & Equity Statement

The Equality and Equity Assessments for this policy will be undertaken at CCG level. Please contact the relevant London CCG for further details of their Equality Impact Assessment.

Governance statement

In mid-2017, London's CCG Chief Officers supported a pan London programme to ensure equitable treatment access for all Londoners that is consistent, clinically appropriate and based on robust evidence that supports improved patient outcomes for certain treatments across London.

NHS England (London) commissioned Healthy London Partnership (HLP) to facilitate the programme management and communications work of the programme, known as 'London Choosing Wisely'. A London Choosing Wisely Steering Group was formed, chaired by the NHSE (London) Medical Director, Dr Vin Diwakar, and included clinical leaders representing each sustainability and transformation partnership (STP), the clinical leads appointed to the review of each area of care, patient representatives, and public health experts.

The London Choosing Wisely programme specifically looked at the following eight procedures: the surgical removal of benign skin lesions; hip arthroplasty; knee arthroplasty; knee arthroscopy; interventional treatments for back pain; varicose vein procedures; shoulder decompression and cataract surgery.

Six Task and Finish Groups were established to review the evidence and draft the policy documentation for each of the eight identified procedures (with hip and knee policies being considered together). Each group was chaired by a primary care clinical lead, who also sat on the Steering Group. All groups included primary and secondary care clinicians and patient representatives from across the London region and were supported by independent public health experts. Upon consideration of the evidence, the Task and Finish Group drafted and agreed the commissioning policy which was subsequently presented to the Steering Group for approval. The Steering Group's role was to ensure that a robust and rigorous review process had been carried out and to agree a final draft for each pan London policy.

Glossary

Institute for Clinical and Economic Review (ICER): non-profit organization in the US that aims to evaluate evidence of the value of medical tests, treatments and delivery system innovations that can be used to improve and inform the healthcare system.

MBR: multidisciplinary biopsychosocial rehabilitation

Numeric rating scale (NRS): 11 point scale (0-10) for patient self-reporting pain.

Quality Adjusted Life Year (QALY): A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale). It is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance.

Short form 36 Health survey (SF36): patient-reported, it is a measure of health status and an abbreviated variant of it, the SF-6D. It is commonly used in health economics as a variable in the quality-adjusted life year calculation to determine the cost-effectiveness of a health treatment.

Visual analogue scale (VAS): patient self-reports pain by placing a line perpendicular to the VAS line at the point that represents their pain intensity.



Appendix - Codes for procedures

There are a large number of possible codes, but these have been included so that CCGs have a source from which to derive local arrangements should this be helpful.

OPCS Codes (Procedure codes)	
A521	Therapeutic lumbar epidural injection
A522	Therapeutic sacral epidural injection
A528	Other specified therapeutic epidural injection
A529	Unspecified therapeutic epidural injection
A572	Rhizotomy of spinal nerve root
A573	Radiofrequency controlled thermal destruction of spinal nerve root
A577	Injection of therapeutic substance around spinal nerve root
V251	Primary extended decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V252	Primary extended decompression of lumbar spine NEC
V253	Primary posterior decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V254	Primary posterior laminectomy decompression of lumbar spine
V255	Primary posterior decompression of lumbar spine NEC
V256	Primary lateral foraminotomy of lumbar spine
V257	Primary anterior corpectomy of lumbar spine and reconstruction HFQ
V258	Other specified primary decompression operations on lumbar spine
V259	Unspecified primary decompression operations on lumbar spine
V261	Revisional extended decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V262	Revisional extended decompression of lumbar spine NEC
V263	Revisional posterior decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V264	Revisional posterior laminectomy decompression of lumbar spine
V265	Revisional posterior decompression of lumbar spine NEC
V266	Revisional lateral foraminotomy of lumbar spine
V267	Revisional anterior corpectomy of lumbar spine and reconstruction HFQ
V268	Other specified revisional decompression operations on lumbar spine
V269	Unspecified revisional decompression operations on lumbar spine
V281	Primary insertion of lumbar interspinous process spacer
V282	Revisional insertion of lumbar interspinous process spacer
V288	Other specified insertion of lumbar interspinous process spacer
V289	Unspecified insertion of lumbar interspinous process spacer
V331	Primary laminectomy excision of lumbar intervertebral disc
V332	Primary fenestration excision of lumbar intervertebral disc
V333	Primary anterior excision of lumbar intervertebral disc and interbody fusion of joint of lumbar spine
V334	Primary anterior excision of lumbar intervertebral disc NEC
V335	Primary anterior excision of lumbar intervertebral disc and posterior graft fusion of joint of lumbar spine
V336	Primary anterior excision of lumbar intervertebral disc and posterior instrumentation of lumbar spine

V337	Primary microdiscectomy of lumbar intervertebral disc
V338	Other specified primary excision of lumbar intervertebral disc
V339	Unspecified primary excision of lumbar intervertebral disc
V341	Revisional laminectomy excision of lumbar intervertebral disc
V342	Revisional fenestration excision of lumbar intervertebral disc
V343	Revisional anterior excision of lumbar intervertebral disc and interbody fusion of joint of lumbar spine
V344	Revisional anterior excision of lumbar intervertebral disc NEC
V345	Revisional anterior excision of lumbar intervertebral disc and posterior graft fusion of joint of lumbar spine
V346	Revisional anterior excision of lumbar intervertebral disc and posterior instrumentation of lumbar spine
V347	Revisional microdiscectomy of lumbar intervertebral disc
V348	Other specified revisional excision of lumbar intervertebral disc
V349	Unspecified revisional excision of lumbar intervertebral disc
V351	Primary excision of intervertebral disc NEC
V352	Revisional excision of intervertebral disc NEC
V358	Other specified excision of unspecified intervertebral disc
V359	Unspecified excision of unspecified intervertebral disc
V363	Prosthetic replacement of lumbar intervertebral disc
V382	Primary posterior interlaminar fusion of joint of lumbar spine
V383	Primary posterior fusion of joint of lumbar spine NEC
V384	Primary intertransverse fusion of joint of lumbar spine NEC
V385	Primary posterior interbody fusion of joint of lumbar spine
V386	Primary transforaminal interbody fusion of joint of lumbar spine
V388	Other specified primary fusion of other joint of spine
V389	Unspecified primary fusion of other joint of spine
V393	Revisional posterior interlaminar fusion of joint of lumbar spine
V394	Revisional posterior fusion of joint of lumbar spine NEC
V395	Revisional intertransverse fusion of joint of lumbar spine NEC
V396	Revisional posterior interbody fusion of joint of lumbar spine
V397	Revisional transforaminal interbody fusion of joint of lumbar spine
V398	Other specified revisional fusion of joint of spine
V399	Unspecified revisional fusion of joint of spine
V404	Posterior instrumented fusion of lumbar spine NEC
V411	Posterior attachment of correctional instrument to spine
V418	Other specified instrumental correction of deformity of spine
V433	Excision of lesion of lumbar vertebra
V473	Biopsy of lumbar vertebra
V481	Radiofrequency controlled thermal denervation of spinal facet joint of cervical vertebra
V485	Radiofrequency controlled thermal denervation of spinal facet joint of lumbar vertebra
V486	Denervation of spinal facet joint of lumbar vertebra NEC
V487	Radiofrequency controlled thermal denervation of spinal facet joint of vertebra NEC
V488	Other specified denervation of spinal facet joint of vertebra
V489	Unspecified denervation of spinal facet joint of vertebra
V493	Exploratory lumbar laminectomy

V508	Other specified manipulation of spine
V509	Unspecified manipulation of spine
V544	Injection around spinal facet of spine
V583	Primary automated percutaneous mechanical excision of lumbar intervertebral disc
V588	Other specified primary automated percutaneous mechanical excision of intervertebral disc
V598	Other specified revisional automated percutaneous mechanical excision of intervertebral disc
V603	Primary percutaneous decompression using coblation to lumbar intervertebral disc
V613	Revisional percutaneous decompression using coblation to lumbar intervertebral disc
V671	Primary posterior lumbar medial facetectomy
V672	Primary hemilaminectomy decompression of lumbar spine
V678	Other specified other primary decompression operations on lumbar spine
V679	Unspecified other primary decompression operations on lumbar spine
V681	Revisional posterior lumbar medial facetectomy
V682	Revisional hemilaminectomy decompression of lumbar spine
V688	Other specified other revisional decompression operations on lumbar spine
V689	Unspecified other revisional decompression operations on lumbar spine
W903	Injection of therapeutic substance into joint
X306	Injection of anaesthetic agent NEC
X308	Other specified injection of therapeutic substance
X309	Unspecified injection of therapeutic substance
X375	Intramuscular injection of therapeutic substance
Z063	Lumbar spinal cord
Z064	Meninges of spinal cord
Z068	Specified spinal cord NEC
Z069	Spinal cord NEC
Z073	Spinal nerve root of lumbar spine
Z677	Coccyx

With the following ICD-10 diagnosis code(s):

S39.01 2	Low back strain
M51.0	Lumbar and other intervertebral disc disorders with myelopathy
M51.1	Radiculopathy – lumbar and other intervertebral disc disorder
M51.2	lumbago due to intervertebral disc displacement
M51.3	Other specified intervertebral disc degeneration
M54.3	Sciatica
M54.4	lumbago with sciatica
M54.9	Dorsalgia
M55.5	low back pain
G54.4	Lumbosacral root disorders, not elsewhere specified
G54.1	Lumbosacral plexus disorders
G55.1	Nerve root and plexus compressions in intervertebral disc disorders

For procedures using US or X-ray guidance, the following codes can be added directly after the main procedure	
Y532	Ultra Sound scan
Y531	X-ray
Z673	Cervical
Z674	Thoracic
Z675	Lumbar
Z942	Right
Z943	Left
Z941	Bilateral

Appendix – Full Evidence Review London Choosing Wisely

Guidance Review Summary:

Interventional treatments for back pain

Version	Date	Notes
Draft for T&F 1	12/4/18	Initial draft
Revised version following Public Health and Chair's review	17/4/18	Minor changes to structure for T&F group
Revised version following first Task & Finish Group Meeting	04/05/18	Spinal cord stimulation information in summary table amended as per direction from T&F group
Amended	31/07/18	To include details of search terms from search strategy document, following LCW steering group meeting of 30/07/18
Final	20/08/18	Text added to search strategy section following discussion at July Steering group meeting.

Introduction

<p>What?</p>	<p>This review will focus on the specific interventional treatments for back proposed by the London Choosing Wisely team.</p> <p>The aim of this review is to present the available guidance to the Task and Finish group in order to support informed decision making regarding commissioning policy.</p> <p>Patients with malignancy or suspected malignancy should be referred via the two-week wait pathway and are not covered by this evidence review. Patients with neurological deficit (spinal cord compression or cauda equina symptoms), fracture or infection are also excluded from this evidence review.</p> <p>Specifically covered by this evidence review are epidurals, spinal injections, spinal fusion and spinal decompression. Also covered are sacroiliac joint injections, radiofrequency denervation, disc replacement, spinal cord stimulation and acupuncture.</p> <p>The list of OPCS codes relevant to this evidence review are included in Appendix 3.</p>
<p>Who for?</p>	<p>The evidence review includes adults over 16.</p>
<p>Why?</p>	<p>Back pain is very common, especially as a presentation to General Practice, and usually self-limiting. It is also important to recognise that 'back pain' itself has a wide-ranging definition, covering a number of different diagnoses. There is a smaller proportion of patients within this with 'red flag' symptoms, who may need different management, including specialist opinion, diagnostic tests or further treatment.</p> <p>Currently much health service resource is utilised to provide very little positive benefit for patients. However, it can lead to considerable disability, in part through well-intentioned over-medicalisation of initial care management.</p> <p>The condition has a huge cost to the individual, society and the country's economy. Therefore, it is important to review up to date existing guidance relating to interventional treatments for back pain in order to inform later development of policy. Ultimately, this can help to ensure the right care can be provided for the right patient at the right time.</p>
<p>Why an issue?</p>	<p>Some London CCGs have commissioning policies relating to interventional treatments for back pain:</p> <ul style="list-style-type: none"> - BHR (Barking, Havering and Redbridge) - NCL (Barnet, Camden, Enfield, Haringey, Islington) - SWL (Croydon, Kingston, Merton, Richmond, Sutton, Wandsworth) <p>The extant policies in these CCGs currently vary in their inclusion criteria and types of procedure they cover.</p> <p>Other CCGs do not any commissioning policy relating to interventional treatments for back pain:</p> <ul style="list-style-type: none"> - WELC (City & Hackney, Newham, Tower Hamlets, Waltham Forest) - South East London (Bexley, Bromley, Greenwich, Lambeth, Lewisham, Southwark).

	<ul style="list-style-type: none">- NWL (Brent, Central, Ealing, Hammersmith & Fulham, Harrow, Hillingdon, Hounslow, West London).
Who else does what?	<p>As there are policy discrepancies, there is potential for patients to not be receiving equal access to treatments across London</p> <p>See Appendix 2 for a detailed table of current CCG policies relating to interventional treatments for back pain.</p>

Search strategy

The London Choosing Wisely team drafted the proposed scope, following which views were sought from the wider membership; including GP and Consultant representatives across London.). In line with the scope agreed for this work, the literature review was intended to focus on collating information across existing CCG policies and reviewing approximately 5 research papers (level 1 policy group).

- The evidence review will collate relevant evidence, so far as it is available, from the named sources. The intention is to cover the following interventions:
Epidurals / nerve root blocks
 - Spinal injections
 - Spinal Fusion
 - Spinal decompression
 - Sacro-iliac joint injections
 - Radio frequency denervation
 - Disc replacement
 - Spinal cord stimulation
 - Acupuncture.

In order to cover a breadth of procedures, this review focuses on guidance from three specific sources, of which views were sought on from the Task & Finish group:

- NICE guidance (*Low back pain and sciatica in over 16s: assessment and management invasive treatments*, Nov. '16).
- Lancet paper (*Low back pain 2: Prevention and treatment of low back pain: evidence, challenges, and promising directions*, Mar. '18).
- NHSE National Low Back and Radicular Pain Pathway 2017.

Search Terms

Low back pain and/or sciatica in the NICE guidance and Lancet paper detailed above.

All terms related to the following interventional back pain treatments:

- Epidurals
- Spinal injections
- Spinal fusion
- Spinal decompression
- Sacro-iliac joint injections
- Radiofrequency denervation
- Disc replacement
- Spinal cord stimulation
- Acupuncture

Exclusions:

- Children.
- Patients thought to have/have cancer (including metastatic spinal cord compression), neurological deficit (spinal cord compression or cauda equina symptoms), fracture or infection.

Search methods

Due to the breadth of procedures, the three sources accepted by the Task and Finish Group above have been used for this review. A summary of existing CCG policies (where available) across London have also been included in the appendix.

The hierarchy of evidence is detailed below, with Level 1 evidence providing the highest quality. We have not gone back to original sources as the methodology used by NICE in particular sets this out in the detailed appendices to the guidance.

NICE’s work used the GRADE system, which does not map directly to this but is an alternate recognised approach to categorization of quality.

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	
Other	National and International Guidance	<ul style="list-style-type: none"> • NICE guidance (<i>Low back pain and sciatica in over 16s: assessment and management invasive treatments</i>, Nov. '16). • Lancet paper (<i>Low back pain 2: Prevention and treatment of low back pain: evidence, challenges, and promising directions</i>, Mar. '18). • NHSE National Low Back and Radicular Pain Pathway 2017.

This table summarises the findings. Please find the detailed review on following pages

Summary of findings

	Potential specific use	Limited evidence	Not effective	NICE's rating of quality of evidence	Key points
Epidurals (Interlaminar, transforaminal, caudal)	✓			<ul style="list-style-type: none"> 12 randomised control trials (RCTs) 2 economic evaluations 	<p>NICE and NHSE guidance in agreement:</p> <ul style="list-style-type: none"> Do not use epidural injections for neurogenic claudication in people who have central spinal canal stenosis. Consider epidural injections of local anaesthetic + steroid in those with acute and severe sciatica. <ul style="list-style-type: none"> Acute sciatica population (symptoms <3months), multiple injections would not be performed in such a short time. <p>Lancet:</p> <ul style="list-style-type: none"> Recognises there may be limited use in selected patients with persistent low back pain >12 weeks.
Spinal injections (facet joint injections, medial branch blocks, intradiscal therapy, prolotherapy, trigger point injections)			✓	<ul style="list-style-type: none"> 31 studies No economic evaluations 	<p>NICE and NHSE guidance in agreement:</p> <ul style="list-style-type: none"> Do not offer spinal injections for managing low back pain. <p>Lancet:</p> <ul style="list-style-type: none"> Recent guidelines do not recommend spinal epidural injections or facet joint injections for low back pain Epidural injections of local anaesthetic and steroid for severe radicular pain may have a role (as above)
Spinal fusion			✓	<ul style="list-style-type: none"> 9 studies 2 economic evaluations 	<p>NICE and NHSE guidance in agreement:</p> <ul style="list-style-type: none"> Do not offer spinal fusion for people with low back pain unless as part of a randomized control trial. <p>Lancet:</p> <ul style="list-style-type: none"> Insufficient evidence for acute non-radicular low back pain with degenerative disc findings (<6 weeks) and role uncertain for persistent non-radicular low back pain with degenerative disc

					<p>findings (>12 weeks).</p> <ul style="list-style-type: none"> Benefits of spinal fusion for non-radicular low back pain thought to originate from degenerated lumbar discs are similar to those of intensive multidisciplinary rehabilitation and only modestly greater than standard non-surgical management. Surgery is also more costly and carries a greater risk of adverse events than non-surgical management. .
Spinal decompression		✓		<ul style="list-style-type: none"> 9 RCTs 4 cohort studies 3 economic evaluations 	<p>NICE and NHSE are in agreement:</p> <ul style="list-style-type: none"> Consider spinal decompression for people with sciatica when non-surgical treatment has not improved pain or function and their radiological findings are consistent with sciatic symptoms. <p>Lancet:</p> <ul style="list-style-type: none"> Spinal decompression surgery can be considered for radicular pain when non-surgical treatments have been unsuccessful and clinical and imaging findings indicate association of symptoms with herniated discs or spinal stenosis. For a herniated disc, early surgery is associated with faster relief of radiculopathy than with initial conservative treatment with the option of delayed surgery, but benefits diminish with longer (>1 year) follow-up. For symptoms associated with lumbar spinal stenosis, benefits of surgery over conservative care are not clear but some beneficial effects have been shown. However, patients tend to improve with or without surgery and, therefore, non-surgical management is an appropriate option for patients who wish to defer or avoid surgery.
Sacro-iliac joint injections					No evidence from NICE/Lancet/NHSE.
Radiofrequency denervation	✓			<ul style="list-style-type: none"> 8 RCTs 1 economic evaluation 1 further original NICE commissioned economic evaluation 	<p>NICE and NHSE are in agreement:</p> <ul style="list-style-type: none"> Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when: <ul style="list-style-type: none"> Non-surgical treatment has not worked on 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 localized back pain (rated as 5 or more on a visual analogue scale, or

					<p>equivalent) at the time of the referral.</p> <ul style="list-style-type: none"> • Only perform radiofrequency denervation in people with chronic low back pain after a positive response to a diagnostic medial branch block. • No repeat radiofrequency denervation should be considered if the benefit is for less than 16 months (NICE NH59 cost effectiveness)¹. <p>Lancet</p> <ul style="list-style-type: none"> • The UK guideline suggests consideration of radiofrequency denervation for chronic low back pain that is unresponsive to non-surgical treatments; however, the subsequently published MINT trials challenge this recommendation.
Disc replacement			✓	<ul style="list-style-type: none"> • 5 RCTs • 2 cohort studies • 1 economic evaluation 	<p>NICE and NHSE are in agreement:</p> <ul style="list-style-type: none"> • Do not offer disc replacement in people with low back pain. <p>Lancet:</p> <ul style="list-style-type: none"> • The UK guidelines recommend that patients do not have disc replacement or spinal fusion surgery for low back pain, and instead recommend offering fusion surgery only as part of a randomized trial.
Acupuncture			✓	<ul style="list-style-type: none"> • Not available 	<p>NICE and NHSE guidance in agreement:</p> <ul style="list-style-type: none"> • Do not offer acupuncture for managing low back pain with or without sciatica. • NHSE further recommends to decommission treatments which are recommended against by NICE 2016, such as acupuncture. <p>Lancet:</p> <ul style="list-style-type: none"> • Recommends acupuncture for acute low back pain (<6 weeks) and persistent low back pain (>12 weeks) as a second line or adjunctive treatment.

Appendices

¹ Full text from p58 of the full NICE guideline of 30 Nov 2016 – Drawn from the section on economic modelling –

“Radiofrequency denervation remains cost-effective at a threshold of £20,000 per QALY in all sensitivity analyses, except if the duration of radiofrequency denervation is less than 16 months, if the probability of declining radiofrequency denervation is greater than 50% and if the probability of a positive diagnostic block is less than 40%.”

1 – Detailed evidence review

2 – Existing CCG Policies

3 – Proposed OPCS and ICD 10 Codes

4 – Additional evidence review following first Task & Finish Group

Appendix 1 – Detailed evidence review

- The information presented below is an objective summary derived from the three sources included in this review. Particularly, the NICE guidance for each procedure was reviewed in turn and a condensed version of each section is presented below.
- Where possible, the text in the table has directly been taken from the original sources.
- Note: the grading of evidence used in the NICE guidance review is that which was used in the guideline itself, according to the GRADE system.

Procedure	NICE https://www.nice.org.uk/guidance/ng59/resources/low-back-pain-and-sciatica-in-over-16s-assessment-and-management-pdf-1837521693637	Lancet http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30489-6/abstract	NHSE http://www.noebackpainprogramme.nhs.uk/wp-content/uploads/2015/05/National-Low-Back-and-Radicular-Pain-Pathway-2017_final.pdf
Epidurals	<ul style="list-style-type: none"> • Quality of life, pain severity, function and psychological distress outcomes critical for decision-making. • Low or moderate evidence (due to risk of bias usually caused by selection or performance bias, small sample sizes and imprecision) across all outcomes and comparisons in review. • Anti-TNF studies had small sample sizes and some had incomplete reporting of outcome data. <p><u>Epidural injections for sciatica</u> Administration may involve caudal, interlaminar or transforaminal/nerve root/dorsal root ganglion injection.</p> <ul style="list-style-type: none"> • 12 RCTs. • All “critical” outcomes for this section of the review, such as pain, mental health, quality of life etc., were reported across studies. • Four Cochrane reviews, however, stratification of groups unclear therefore not included in review. <p><u>Image guided epidurals</u> <u>Epidural vs Sham/Placebo</u></p> <ul style="list-style-type: none"> • In patients with sciatica, clinical benefit of an anti-TNF epidural vs placebo at 4 months. • Clinical benefit favouring Steroid + anaesthetic to placebo resulting in ≥50% reduction in pain but no difference in function. • No benefit when anaesthetic alone used compared to placebo. 	<ul style="list-style-type: none"> • Recent guidelines do not recommend epidural injections or facet joint injections for low back pain but do recommend consideration of epidural injections of local anaesthetic and steroid for severe radicular pain. • Epidural injections: <ul style="list-style-type: none"> ○ Associated with small short term (<4weeks) reduction in pain ○ Do not seem to provide long term benefits or reduce the long term risk of surgery ○ Have been 	<p><u>Timeline</u></p> <ul style="list-style-type: none"> • For severe, non-controllable radicular pain in prolapsed intervertebral disc early in the course for symptom control • For treatment of lumbar radicular pain with the aim of avoiding surgery – patient and/or clinician choice • Do not sure epidural injection for neurogenic claudication with central spinal stenosis • Utility of diagnostic lumbar nerve root injections has not been fully established. <p><u>Entry criteria</u></p> <ul style="list-style-type: none"> • Clinician and patient agreement for therapeutic injection for moderate or severe lumbosacral radicular pain (compressive or inflammatory) • Lack of suitability of alternative treatments <ul style="list-style-type: none"> ○ Patient unsuitable for surgery ○ Patient unable to tolerate

<ul style="list-style-type: none"> • Not sufficient RCT data and no relevant cohort data to support. <p><u>Epidural vs Active Control</u></p> <ul style="list-style-type: none"> • In those with sciatica primarily caused by >70% prolapse/non-disc lesion/unclear spinal pathology, there was no clinical benefit of steroid + anaesthetic vs anaesthetic alone for pain/function over short/long term. • In addition, no clinical benefit for those treated with anti-TNF + anaesthetic compared to anaesthetic alone at ≤ 4 months. • In those with sciatica caused by >70% prolapse, there was clinical benefit (leg pain, function, quality of life) of steroid + anaesthetic vs non-invasive interventions or anti-TNF + anaesthetic at ≤ 4 months. <p><u>Non-image guided epidurals</u></p> <ul style="list-style-type: none"> • 15 RCTs were included. • All critical outcomes reported across studies, except quality of life. <p><u>Epidural vs Sham/Placebo</u></p> <ul style="list-style-type: none"> • No clinical benefit of steroid vs placebo for function at >4 months/up to 4 months. • Steroid + anaesthetic – no clinical benefit with pain/function at short and long term follow-up. <p><u>Epidural vs Active Control</u></p> <ul style="list-style-type: none"> • In those with sciatica (unclear pathology), there was clinical benefit of steroid vs usual care for leg pain and function at up to 4 months but not >4 months. • In those with sciatica primarily caused by >70% prolapse, no clinical benefit of steroid + anaesthetic vs pharmacological treatments (NSAIDs) for pain/function at up to 4months or for pain when compared with a combination of pharmacological interventions at short and long term follow-up. • In those with sciatica primarily caused by >70% prolapse, there was clinical benefit of steroid + anaesthetic compared to anaesthetic alone at up to 4months (when Methylprednisolone/Triamcinolone + Bupivacaine, not with Dexamethasone + Bupivacaine). <p><u>Economic evaluations</u></p> <ul style="list-style-type: none"> • Two economic evaluations were included in this review. • One cost utility analysis found non-image guided epidural injections of steroid + anaesthetic was not cost effective vs 	<p>associated with rare but serious adverse events, including loss of vision, stroke, paralysis and death.</p> <p><u>Recommendations</u></p> <ul style="list-style-type: none"> • Epidural glucocorticoid injection (for herniated disc with radiculopathy) <ul style="list-style-type: none"> ○ Acute low back pain (<6 weeks) – not recommended ○ Persistent low back pain (>12 weeks) – limited use in selected patients. 	<p>neuropathic pain medications</p> <ul style="list-style-type: none"> ○ Informed consent. <p><u>Exclusion criteria</u></p> <ul style="list-style-type: none"> • Neurogenic claudication in those with central spinal cord stenosis • Local/systemic infection • Patient unwilling/lack of cooperation to tolerate procedure. <p><u>Interventions</u></p> <p>Consider epidural injection of local anaesthetic + steroid in people with acute severe radicular pain</p> <ul style="list-style-type: none"> • Interlaminar, transforaminal, caudal • Nerve root injection • Combine epidural/nerve root injection with appropriate medication management, physical and psychological therapies to maximize benefit. <p><u>Definition satisfactory result</u></p> <ul style="list-style-type: none"> • If for severe early pain <ul style="list-style-type: none"> ○ Length of time with tolerable pain ○ % referred for surgery • If as treatment for lumbar radicular pain with aim of avoiding surgery <ul style="list-style-type: none"> ○ % avoiding surgery • Return to work • Improved EQ5D/Back Specific Disability Score • Patient reported improvement / satisfaction • Patient choice to self-manage
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	<p>placebo. This analysis was assessed as partially applicable with potentially serious limitations.</p> <ul style="list-style-type: none"> • One cost effectiveness analysis found that non-image guided steroid epidural was more costly and more effective than placebo for adults with sciatica (ICER: £60 per 1 appointment in NRS back pain score). This analysis was assessed as partially applicable with potentially serious limitations. <p><u>Key Points</u></p> <ul style="list-style-type: none"> • Evidence for effectiveness of epidurals conflicting. • Sciatic symptoms usually improve over a few months in majority without treatment. • Placebo controlled trials showed some evidence of effect for epidurals, especially steroid + anaesthetic. <ul style="list-style-type: none"> ◦ Evidence suggested key component was steroid but no evidence of benefit of steroid/anaesthetic alone when compared with sham/placebo. • 2 trials showed that 50% of people who had an epidural did not go on to have surgery. Therefore, in acute/severe sciatica, where patients would otherwise be offered surgery, epidural injection to be considered. • Insufficient/lack of evidence for use of anti-TNF. • Most of the RCT evidence came from people with acute and moderately severe sciatica, therefore this was considered to be the population that would most likely benefit from an epidural injection. • Limited evidence of difference between image/non-image guided epidural injections, however, safety should be considered. <p><u>NICE Recommendations</u></p> <ul style="list-style-type: none"> • Consider epidural injections of local anaesthetic + steroid in those with acute and severe sciatica. <ul style="list-style-type: none"> ◦ Acute sciatica population (symptoms <3months), multiple injections would not be performed in such a short time. • Do not use epidural injections for neurogenic claudication in those with spinal cord stenosis. • Equally apply to pregnant women, in line with BNF recommendations. • There is a rationale that transforaminal epidurals (requires 		
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	<p>imaging – potentially limiting access and increasing cost) might be most effective, by ensuring delivery of substances directly to the region in which the nerve root might be compromised.</p> <ul style="list-style-type: none"> • People who do not respond to caudal injection may be offered image guided transforaminal injection later. People may therefore currently experience unnecessary symptoms at unnecessary cost to the NHS 		
Spinal injections	<p>These include facet joint injections, medial branch blocks, intradiscal therapy.</p> <ul style="list-style-type: none"> ○ Prolotherapy and trigger point injections are also considered in this part of the guidance. • Usually, injected agents aim to sooth inflamed tissue or calm excessive nerve activity, but some (sclerosants) aim to induce inflammation and stimulate healthy new tissue growth. • Guidance addresses effectiveness of various agents, rather than route or mode of administration. • 31 studies included were included in the review. • Four Cochrane reviews, however, stratification of groups unclear therefore not included in review. • No relevant economic evaluations were identified. • Evidence was reported for all outcomes except psychological distress and healthcare utilization. <p><u>Image guided facet joint injections</u> <u>Steroid vs Saline</u></p> <ul style="list-style-type: none"> • In patients with low back pain, clinical benefit for pain >4months but not ≤4 months. • Similar for function but baselines very low therefore unlikely much improvement could be demonstrated from the baseline. • Lack of short-term effect with some evidence of long-term effect raised some doubt on the long-term effect being solely due to injection. • Facet joint injection widely used but paucity of evidence. No evidence of clinical harm from the studies reviewed. <p><u>Steroid vs Hyaluronans</u></p> <ul style="list-style-type: none"> • Very low quality evidence showed clinical benefit from steroids in short term with no clinically important difference between treatments in any other outcome reported at short/long term. 	<p>Recent guidelines do not recommend spinal epidural injections or facet joint injections for low back pain but EU, US and UK guidelines recognize that epidural injections of local anaesthetic and steroid for severe radicular pain may be considered.</p> <p>Interventional procedures are also overused, with studies showing 990 449 lumbar or sacral facet injections and 406 378 lumbar or sacral facet neurotomy procedures funded by Medicare in the USA in 2011.</p>	<p>NICE 2016 recommended against spinal injections for managing low back pain.</p> <p>National Back Pain Pathway stakeholders agreed to adopt NICE recommendation.</p> <p>To decommission treatments which are recommended against by NICE 2016 such as therapeutic injections for back pain including facet joint injections.</p>

	<ul style="list-style-type: none"> • Also, note Hyalurons may cause inflammation and therefore an increase in pain. <p><u>Steroid + Biomechanical exercise vs Biomechanical exercise</u></p> <ul style="list-style-type: none"> • No clinically important difference (1 trial). <p><u>Steroid + Anaesthetic + Biomechanical exercise vs Biomechanical exercise</u></p> <ul style="list-style-type: none"> • Very low quality non randomized evidence from a very small trial demonstrated clinical benefit in pain seen in short and long term but not in function. • Low to very low quality evidence overall. <p><u>Other image guided injections</u></p> <p><u>Steroid (Dexamethasone or Betamethasone) vs saline</u></p> <ul style="list-style-type: none"> • 3 studies: clinical benefit in pain and function favouring use of steroid injection intradiscally in short and long term. • 1 study in China and may not be relevant to UK population. Potential risk for harm also highlighted, i.e. risk of infection/disc prolapse. • Steroid (Betamethasone) (2 studies – very low quality): clinical benefit for pain and function in the long term. Not observed for Methylprednisolone or Dexamethasone. <p><u>Steroid + Anaesthetic vs Anaesthetic</u></p> <ul style="list-style-type: none"> • 3 studies of moderate quality evidence showed no clinically important difference for all outcomes irrespective of route (caudal epidural/medial/interlaminar). • Low or very low quality evidence, mainly due to risk of bias. <p><u>Prolotherapy</u></p> <p><u>Sclerosant vs Anaesthetic (1 very small trial) or Sclerosant + Anaesthetic vs Anaesthetic:</u></p> <ul style="list-style-type: none"> • No clinically important difference in long term. No data for short term. <p><u>Sclerosant + Anaesthetic vs Saline</u></p> <ul style="list-style-type: none"> • (1 study low to moderate quality): clinical benefit in improving pain and function in short and long term. People in intervention group also received a forceful manipulation, therefore unclear benefit solely due to spinal injection. • Sclerosant not licensed for as injection agents in UK. Not enough evidence to recommend for low back pain. 		
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	<p><u>Other non-image guided injections</u> <u>Botulinum toxin vs Saline</u></p> <ul style="list-style-type: none"> (1 study moderate quality): clinical benefit for pain <p><u>Steroid + Anaesthetic vs Steroid</u></p> <ul style="list-style-type: none"> Very low quality evidence study: no clinically important difference in pain short/long term. <p><u>Key points</u></p> <ul style="list-style-type: none"> No consistent good quality evidence to recommend use of spinal injections for the management of low back pain. Minimal evidence of benefit and reason to believe risk of harm, even if rare. <p><u>NICE Recommendations</u></p> <ul style="list-style-type: none"> Do not offer spinal injections for managing low back pain. 		
Spinal fusion	<p>Operation performed to achieve solid bone union between spinal vertebrae to prevent movement. Involves using patient's own bone or artificial bone substitutes. It is commonly carried out as a component part of many types of spinal operation; operations to correct deformity remove tumours and treat spinal fractures.</p> <p>In clinical practice, spinal fusion is sometimes used to treat severe and constant low back pain that has not resolved with more conservative treatments.</p> <p>There are different surgical approaches to the spine: from the back/front/side. Outcomes from different approaches are similar but risks of harm vary according to approach and specific method used.</p> <ul style="list-style-type: none"> 9 studies found in 18 papers <ul style="list-style-type: none"> 1 RCT spinal fusion vs usual care. 1 cohort study fusion vs usual care 1 Cochrane review but not include as stratification of patient groups not clear. Failure rate was the only important outcome for which there was no evidence from studies included in the review. 2 economic evaluations that included spinal fusion as a comparator. 	<p>Spinal fusion for non-radicular low back pain with degenerative disc findings</p> <ul style="list-style-type: none"> Acute low back pain (<6 weeks) – insufficient evidence. Persistent low back pain (>12 weeks) role uncertain. <p>The benefits of spinal fusion surgery for non-radicular low back pain thought to originate from degenerated lumbar discs (known as discogenic) are similar to those of intensive multidisciplinary rehabilitation and only modestly greater than standard non-surgical management. Surgery is</p>	<p>Do not refer for spinal fusion (unless part of a RCT) or disc replacement, as per NICE guidance.</p>

	<p><u>Fusion vs usual care</u></p> <ul style="list-style-type: none"> • 1 randomised study showed clinical benefit of spinal fusion for pain > 4months and for function (GFS and MVAS) in the long term (very low and low quality evidence from single large trial). Difference in pain scores at end of 2years was not very pronounced. Did show marked decrease in pain severity in first 6 months post-op in graphical form – could be result of application of rigid plastic brace restricting individual’s movement after surgery. 17% complication rate and 8% reoperation rate, therefore risk of harm. However, function measured by ODI at >4months showed no clinical difference between fusion and usual care. <ul style="list-style-type: none"> ○ Control group appeared to be a severely disadvantaged group that had not been offered a treatment and had been selected on the grounds of strict inclusion criteria of mandatory sick leave/equivalent disability for a year and previous failure of non-surgical treatment. Could result in risk of bias through ‘negative contextual effect’. ○ Evidence from a non-randomised study for the same comparison suggested no clinical difference between fusion and usual care for any of the reported outcomes. <p><u>Fusion vs other treatment</u></p> <ul style="list-style-type: none"> • 3 studies (1 with intensive MBR of 75h/week, others with 25h/week) consistently showed no clinical difference between spinal fusion and 3 element MBR in pain and function. Overall, no clinical difference between the 2 interventions for majority of QoL domains and composite mental/physical health scores/health utilization scores. Clinical benefit favouring spinal fusion in domains of general health perception and pain. <ul style="list-style-type: none"> ○ 1 small study comparing spinal fusion with minimally treated patients found clinical benefit in pain and function in long term. However, unlikely improvement would be seen as minimally treated patients and very small study compared to 3 other larger studies. ○ Majority of evidence of very low quality due to risk of bias and imprecision. ○ Overall, it appeared MBR programmes perform as well as spinal fusion in terms of improving pain, function 	<p>also more costly and carries a greater risk of adverse events than non-surgical management.</p> <p>The UK guidelines recommend that patients are not offered disc replacement or spinal fusion surgery for low back pain, and instead recommend offering fusion surgery only as part of a randomised trial. Patients with severe or progressive neurological deficits require surgical referral.</p> <p>For symptoms associated with lumbar spinal stenosis, benefits of surgery over conservative care are not clear but some beneficial effects have been shown. However, patients tend to improve with or without surgery and, therefore, non-surgical management is an appropriate option for patients who wish to defer or avoid surgery.</p> <p>Surgery has, at best, a very limited role for low back pain, but studies from the USA, Australia, and the Netherlands show frequent use of</p>	
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	<p>and QoL but are associated with a low risk of harm.</p> <ul style="list-style-type: none"> ○ Single study spinal fusion vs mixed modality exercise showed clinical benefit for fusion in both pain and function at 4months, 1year and 2yr follow up. <p><u>Fusion vs disc replacement</u></p> <ul style="list-style-type: none"> ● 2 studies (randomized large trials) spinal fusion vs disc replacement showed no clinical difference for pain/function in short/long term. Spinal fusion to be less effective in improving QoL at >4months. Disc replacement favoured by physical component in short and long term. No difference for mental component score. <ul style="list-style-type: none"> ○ Low-very low quality evidence due to very high risk of bias, lack of blinding and incomplete data at follow-up. Suggested clinical benefit favouring disc replacement for QoL at Year 1, which was not maintained at Year 2. ○ Conflicting evidence for adverse events from 2 studies. Majority showed no clinical difference between fusion and disc replacement for mortality, complications and reoperation rates at 2 and 5years. However, fusion reported to have fewer complications at 5 years in 1 study. In contrast, fusion was demonstrated to result in more occurrences of surgery at adjacent level at 2 years compared to disc replacement (1 study very low quality). ○ Estimated 10-20% rate of complication across studies, 4-5% = serious complications. High rate of serious complications associated with both treatments, e.g. 1 study reported 345/405 experienced adverse events 2years following fusion surgery. Intraoperative serious complications varied: 14.6% disc replacement (more invasive), 8.7% spinal fusion. ○ Therefore, clinical benefit favouring disc replacement assessed by physical component in both short and long term significant enough to outweigh potential harm, despite effect being maintained at 1 and 2years. <p><u>Economic</u></p> <ul style="list-style-type: none"> ● 1 cost utility analysis (Fritzell 2011) found that spinal fusion was dominated (more costly and less effective) compared to disc replacement for treating low back pain with/without 	<p>spinal fusion.</p> <p>The growing use of complex fusion procedures in patients older than 60 years undergoing decompressive surgery for spinal stenosis is concerning, since fusion operations are three times more expensive than decompression alone, and have double the rates of wound complications, cardiopulmonary complications (such as stroke), and 30-day mortality. Importantly, trials have clarified that adding fusion to decompressive surgery for symptomatic spinal stenosis does not improve outcomes.</p>	
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	<p>sciatica.</p> <ul style="list-style-type: none"> ○ Within trial analysis (RCT: Berg 2009). All cost elements were higher for the spinal fusion group and that one of the key cost driver was the higher rate of re-operations in the spinal fusion surgery group. • 1 cost utility analysis (Rivero Arias 2005) found that spinal fusion was not cost-effective compared to a 3-element MBR programme (ICER: £48,515 QALY gained). <ul style="list-style-type: none"> ○ Within trial analysis (RCT: Fairbank 2005). High cross over between treatment arms reported in trial, resulting in large proportion of trial participants receiving both interventions by the end of the 2 year follow-up. • Unit cost for spinal fusion surgery estimated at £7,337/patient. Based on weighed average for complications and co-morbidities of various HRG codes. Same cost for disc replacement as same HRG codes. <p><u>Key Points</u></p> <ul style="list-style-type: none"> • No consistent benefit of spinal fusion over comparator treatments and evidence of potential harm. Therefore, lack of evidence of clinical effectiveness to recommend spinal fusion for people with low back pain other than in context of RCT. • Accepted causes of low back pain for which spinal fusion might be an appropriate treatment, which are beyond the scope of the guideline. • Studies fail to show clear advantage of fusion but do show some modest benefit on some elements of pain, function and QoL, as well as reduction in healthcare utilization. It is not known what treatments should have been tried prior to surgery. <p><u>NICE Recommendations</u></p> <ul style="list-style-type: none"> • Do not offer spinal fusion for people with low back pain unless as part of a randomized control trial. 		
Spinal decompression	Spinal decompression refers to removal of pressure from the nervous structures within the spinal column. An example would be laminectomy, which may also include foraminotomy/trimming of overgrown facets and or discectomy.	Spinal decompression surgery can be considered for radicular pain when non-surgical treatments have been	Sciatica: consider spinal decompression if non-surgical treatment has not improved pain or function, as per NICE guidance.

	<p>Most common cause of spinal canal narrowing is degenerative lumbar disease, otherwise known as spondylosis. Associated symptoms are neurogenic claudication (pain and/or numbness/weakness worse with prolonged standing). Disc prolapse, on the other hand, causes leg pain and sciatica.</p> <ul style="list-style-type: none"> • 9 RCTs published in 14 papers. • 4 further cohort studies included due to insufficient evidence. • Evidence for all critical outcomes except psychological distress. • 2 Cochrane reviews not included because focused on surgery techniques in disc prolapse and not just spinal decompression, and the other review compared different types of spinal decompression techniques. • 3 economic evaluations <p>Discectomy for people suffering from sciatica offered a good prognosis and was successful in providing long term pain relief. However, sciatic symptoms do improve naturally with time without treatment. Earlier symptom resolution with surgical intervention should be an option for people. Agreed sufficient evidence to suggest that discectomy should be considered for a subgroup of people with sciatica who had failed to respond to conservative management of their symptoms.</p> <p><u>Discectomy vs usual care</u></p> <ul style="list-style-type: none"> • Overall, evidence suggested a clinical benefit in favour of discectomy when performed in people with sciatica due to herniated intervertebral disc for QoL assessed by SF36 domains in bodily pain, physical functioning, mental health index, vitality and general health perception in the short term. This benefit was also supported by EQ-5D data at the short term follow up. Noted sciatic symptoms usually improve over the course of first 3 months but this evidence suggested people undergoing discectomy improve quicker. • 2 studies - In people with sciatica due to herniated disc, there was clinical benefit for discectomy compared with usual care for QoL, bodily pain and physical functioning (mental health, vitality and general health for 1 study) at ≤4months. • 2 studies demonstrated clinical benefit in discectomy in QoL at 1y (not physical functioning/mental health). 	<p>unsuccessful and clinical and imaging findings indicate association of symptoms with herniated discs or spinal stenosis. For a herniated disc, early surgery is associated with faster relief of radiculopathy than with initial conservative treatment with the option of delayed surgery, but benefits diminish with longer (>1 year) follow-up.</p> <p>For symptoms associated with lumbar spinal stenosis, benefits of surgery over conservative care are not clear but some beneficial effects have been shown. However, patients tend to improve with or without surgery and, therefore, non-surgical management is an appropriate option for patients who wish to defer or avoid surgery.</p> <p>Surgery has, at best, a very limited role for low back pain, but studies from the USA, Australia, and the Netherlands show frequent use of spinal fusion.</p>	<p><u>Provision of time line (from onset of symptoms)</u></p> <ul style="list-style-type: none"> • Very severe radicular pain which is not controllable with analgesia or nerve root injection may require early surgery likely to be at 1-3week stage • Early surgery at be required if accompanied my major radicular weakness • Otherwise, 8-12weeks if non-tolerable radicular pain • Later surgery may occur in patients with symptoms of fluctuating severity • Neurogenic claudication may be six months. <p><u>Exclusion criteria</u></p> <ul style="list-style-type: none"> • Medically unfit for anaesthetic • Patient does not want to consider surgery • Non-concordant imaging
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	<ul style="list-style-type: none"> • Conflicting evidence demonstrated clinical benefit of discectomy compared with usual care for both leg and back pain in short term but no difference at 1 and 2 years. Further evidence showed no benefit in pain measured by the sciatica bothersome index. • Benefit in function seen at <4months using RMDQ for discectomy but not when using ODI. No difference in function in long term. • 1 study – clinical benefit from discectomy to complete disappearance of symptoms at <4 and >4 months. • Non randomized evidence showed clinical benefit for discectomy for all QoL domains at short and long term follow-up (1 study, very low quality. Benefit for function (ODI) demonstrated for discectomy at short and long term follow up (1 study, low quality). • Non randomized evidence of poorer outcome with discectomy compared to usual care for healthcare utilization assessed by number of patients with more reported diagnostic test use but no clinical difference between treatments for any other healthcare utilization measure. • Function – randomized evidence showed no difference between treatments although non-randomised data suggested clinically important difference favouring discectomy in both short and long term. • Discectomy relatively safe, most common complication = dural tear, could possibly increase length of stay, tear may result in CNS infection. Reoperation rates low – also may be a natural history of the condition since 5% will suffer from a recurrence of disc prolapse. <p><u>Discectomy vs Combination treatment (manual therapy + biomechanical exercise + self-management)</u></p> <ul style="list-style-type: none"> • Conflicting evidence from 1 study for QoL at <4months showed clinical benefit for discectomy for SF-36 domains of bodily pain, vitality and physical function but clinical harm for physical/emotional/social function. No difference between treatments for mental health. Evidence from the same study showed no difference in pain and function between comparators at <4months. <p><u>Percutaneous disc decompression vs usual care</u></p>	<p>The growing use of complex fusion procedures in patients older than 60 years undergoing decompressive surgery for spinal stenosis is concerning, since fusion operations are three times more expensive than decompression alone, and have double the rates of wound complications, cardiopulmonary complications (such as stroke), and 30-day mortality. Importantly, trials have clarified that adding fusion to decompressive surgery for symptomatic spinal stenosis does not improve outcomes.</p>	
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	<ul style="list-style-type: none"> 1 study – clinical benefit for percutaneous disc decompression at both short and long term follow up (low to very low quality). Finding from single study therefore unable to make recommendation based on this limited evidence. <p><u>Plasma disc decompression vs epidural steroid injection</u></p> <ul style="list-style-type: none"> 1 study – clinical benefit in leg and back pain for plasm disc decompression at both short and long term (moderate to low quality). No clinical difference between treatments for function at any point/procedure related adverse events at >4months. Noted that 1 of the inclusion criteria was that the participants had to have dialed a previous epidural injection for the same symptoms between 3 weeks and 6 months previously – considered to be a serious flaw of the trial. No clinically important difference in adverse events. Most adverse events not a cause for concern, except possibly increased weakness seen in the decompression group. <p>Discectomy vs fusion (cohort)</p> <ul style="list-style-type: none"> 1 study (very low quality) – no clinical benefit in function for discectomy at >4months. Patients had to pay for their own surgery, serious limitation of trial as costs for spinal fusion far outweigh that of discectomy. Could potentially skew results in favour of cheaper surgical opinion. <p><u>Laminectomy vs usual care</u></p> <ul style="list-style-type: none"> 1 study – QoL <4months showed laminectomy to be less effective than usual care SF-36 of physical functioning but clinical benefit with laminectomy for domain of bodily pain at long term follow up of 1 and 2 years. Same study – no clinical difference in pain/function at <4 / >4 months (low to very low quality). Non-randomised evidence from a single study demonstrated a clinical benefit of laminectomy for QoL SF-36 of body pain and physical functioning at short and long term (very low quality). Clinical benefit of laminectomy at 1 year but not any other follow up period (low quality). No difference between treatments in leg pain assessed by sciatica bothersome index reported in same study. Clinical benefit with laminectomy seen for function at both <4/>4months follow up (1 study – very low quality). 		
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	<p><u>Economic</u></p> <ul style="list-style-type: none"> • 3 cost utility analyses found that spinal decompression was not cost-effective compared to usual care treating patients with disc herniation or spinal stenosis. • 2 were USA studies based on both randomized and observational cohorts on the SPORT trial. <ul style="list-style-type: none"> ◦ One was adults with intervertebral disc herniation ◦ Other was spinal stenosis without degenerative spondylolisthesis. <p>Cost of surgery much higher in USA. QALY in US was 0.21 and 0.17, whereas 0.044 for Netherlands. Threshold for NICE to consider cost effective = 0.2. Both studies surgery more effective but more costly than usual care with a resulting ICER of >£40k per QALY.</p> <ul style="list-style-type: none"> • 3rd study was a within trial analysis conducted in the Netherlands on a population with disc herniation and lumbosacral radicular syndrome where early microdiscectomy was compared to prolonged conservative care by the GP followed by surgery if sciatica persisted >6months. Surgery was more effective but more costly than usual care. <p>Concluded likely over estimation of cost in US, likely under estimation effectiveness in UK. Therefore, overall, decompression surgery likely to be cost effective in patients with sciatica when other treatments have failed.</p> <p>Key Points</p> <ul style="list-style-type: none"> • Option for earlier pain relief should be available for a subset of patients that suffer from severe, acute sciatic pain. Agreed that surgical intervention following a period of conservative management for around 6 weeks would be reasonable. Noted there was little evidence to support this time point and that the 6 week conservative interval was largely historical and consensus based. As non-surgical management should be pursued prior to surgery, this would negate the need to specify a time point in the recommendation as it is likely that it would be at least 3-6 months before surgery was offered. • Prior imaging was an inclusion criterion for all the studies in the review. Operating without imaging would carry a significant risk of harm. 		
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	<ul style="list-style-type: none"> • If spinal decompression performed, patient outcome information should be submitted to a national registry. • Should equally apply to pregnant women and should be considered in a case by case basis. <p><u>NICE Recommendations</u></p> <ul style="list-style-type: none"> • Consider spinal decompression for people with sciatica when non-surgical treatment has not improved pain or function and their radiological findings are consistent with sciatic symptoms. 		
Sacro-iliac joint injections	n/a	n/a	n/a
Radiofrequency denervation	<p>Some with low back pain may have pain arising from 1 or more spinal structures where nociceptive/pain innervation has been established, e.g. muscles, joints, ligaments and discs. No reliable clinical/radiological features to discriminate between them. Evidence to support idea of back pain arising from discrete structures comes from studies using precisely targeted local anaesthetic blockade.</p> <p>Facet joints are well innervated by the medial branches of the dorsal rami. The prevalence of facet joint pain in heterogeneous populations using local anaesthetic nerve blockades (medial branch block), where 75-100% pain relief is used a criterion standard, is thought to be 25-40%.</p> <p>In current clinical practice, local anaesthetic facet joint nerve blockade to determine the presence/absence of a facet joint pain component. Those who experience significant but short term relief may then be offered a neurodestructive procedure called radiofrequency denervation to attempt longer term pain relief.</p> <ul style="list-style-type: none"> • 8 RCTs • 2 Cochrane review – not included. One included neck and back pain. Other review included low back pain other than facet joint pain. • 1 economic evaluation. • An original economic analysis was prioritized and conducted for this, comparing radiofrequency denervation to usual care. 	<p>The UK guideline suggests consideration of radiofrequency denervation for chronic low back pain that is unresponsive to non-surgical treatments; however, the subsequently published MINT trials challenge this recommendation.</p>	<p>Medial branch block +/- Radiofrequency Denervation</p> <p>Radiofrequency denervation is minimally invasive and percutaneous procedure performed under local anaesthetic or light IV sedation. Radiofrequency energy if delivered along an insulated needle in contact with target nerves. This focused electrical energy heats and denatures the nerve. This may allow axons to regenerate in time, requiring the repetition of the radiofrequency procedure.</p> <p>To ensure that patients with axial back pain are formally assessed with the expectation of undertaking a full spectrum of conservative treatments, including comprehensive multidisciplinary combined physical and psychological programme (CPPP) before referral for consideration of invasive procedures (e.g. spinal surgery or radiofrequency denervation).</p>

	<ul style="list-style-type: none"> • Noted limited data on adverse events from the included evidence, therefore considered it alongside expert opinion and knowledge to inform decision making. • 1 study reported adverse outcomes and there were none in this study. However, noted clinically significant harm for radiofrequency group in terms of treatment related pain (graded as moderate/severe) in short term. Noted some treatment related harm in sham group as well so both groups experienced pain that was considered to be related to the procedure. Study reported 2 adverse events (5%): change of sensibility in radiofrequency denervation group. Important to patient but small rate in study. However, study very small therefore the effect size for these adverse outcomes was considered clinically important. Although allodynia may occur, it is likely to only affect a small number of patients. This risk was concluded as low and the 5% seen in the evidence is higher than would be expected. Benefits in QoL outweighed the risk of harm. • 2 of the studies did not include a true diagnostic medial branch block and this may have result in an unselected patient population. <p><u>Radiofrequency denervation vs placebo for low back pain</u></p> <ul style="list-style-type: none"> • 4 studies clinical benefit in pain with radiofrequency denervation at short and long term. No difference in function between treatments in any point. Baseline in both groups difference initially ad same with 'minimal disability' range post intervention. 1 study – clinical benefit for general health and vitality. Physical function, favour was in placebo group. Noted large baseline differences for physical function between the intervention and sham groups with intervention group 10 points worse at baseline, therefore data showing benefit to placebo group not reliable. Therefore, benefits seen in QoL outweighed the harm. <ul style="list-style-type: none"> ○ 1 study reported adverse events at <4 months and demonstrated an increase in adverse effects for radiofrequency denervation in terms of the number of patients with moderate or severe treatment related pain. No difference in other adverse events in short term. 		<p>An approved intervention later in the pathway for people with mod-severe chronic back pain with clinical features suggestive of a facet joint component, who have had insufficient improvement with comprehensive conservative management.</p> <p>Consider radiofrequency denervation if non-surgical treatments ineffective in chronic LBP.</p> <p>Consider radiofrequency denervation only if positive medial branch block.</p> <p>Do not offer imaging for people with low back pain with specific facet joint pain as prerequisite for radiofrequency denervation.</p> <p>Patients may be referred from GP/Triage/Investigation and Treat Practitioners, Orthopaedic surgeons, Neurosurgeons, Pain Management specialists or any skilled practitioners that has undertaken the appropriate assessment. Patients should be referred if:</p> <ul style="list-style-type: none"> - Patients are considered appropriate for epidural, nerve root block or medial branch blocks/radiofrequency lesioning assessment as part of a MDT management plan. <ul style="list-style-type: none"> • Consider referral for assessment for radiofrequency denervation for people with chronic low back
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	<p><u>Radiofrequency denervation vs medial branch block</u></p> <ul style="list-style-type: none"> 1 study – clinical benefit in radiofrequency denervation at both short and long term follow up for pain. No difference in QoL but data incomplete. However, method did not fit current practice (which would not pre-select those who were most likely to respond to treatment). Also, both groups were given additional therapy in the form of a rehab programme if they showed a post-intervention response. <p><u>Economic</u></p> <ul style="list-style-type: none"> 1 cost consequence (within trial) analysis found radiofrequency denervation more costly and more effective (£186 more per patient) compared to sham for treating low back pain. QALYs not calculated, therefore not possible to judge if it is cost effective. Noted patients did not receive a diagnostic block but rather an intra-articular injection, thus selection of patients does not reflect current practice. Furthermore, intervention cost outlined was lower than current practice. 1 original economic model – radiofrequency denervation more cost effective compared to usual care for treating low back pain suggestive of facet joint origin that has not resolved despite non-invasive management (ICER £11,178). Not enough confidence, however, to make a strong recommendation for this intervention. Also, as low back pain population potentially very large, concern about potential cost impact of a strong recommendation. <p><u>Key Points</u></p> <ul style="list-style-type: none"> Do not offer imaging for people with low back pain with specific facet joint pain as a prerequisite for radiofrequency denervation. All evidence can from populations with chronic pain (ranging from 2-3years or longer) who had failed to respond to conservative treatment. All studies had pain VAS >5 and that this treatment should only be considered for those with pain VAS >5. Agreed that those patients who experience prolonged pain relief from medial branch block should be offered radiofrequency denervation rather than repeated medial branch blocks. 		<p>pain when:</p> <ul style="list-style-type: none"> 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 localized back pain (rated as ≥ 5 on VAS or equivalent) at the time of the referral. <ul style="list-style-type: none"> Clinical features/physical signs of facet joint pain. Features may include: increased pain unilaterally/bilaterally on lumbar paraspinal palpation. <ul style="list-style-type: none"> Increased back pain on 1 or more of the following: extension (more than flexion), rotation, extension/side flexion, extension/rotation. And No radicular symptoms And No sacroiliac joint pain elicited using a provocation test. Only perform radiofrequency denervation in people with chronic low back pain after a positive response to a diagnostic medial branch block with 1ml or less of local anaesthetic at each level (no steroids). Do not offer imaging as prerequisite.
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	<ul style="list-style-type: none"> • Include pregnant women but consider case by case basis. • Concern around potential for re-referrals as some nerve regrowth may be expected after the procedure. • Health economic model suggested that radiofrequency denervation is cost effective over usual care provided the duration of pain relief exceeds 16 months. However, evidence for repeat radiofrequency denervation was not reviewed. • Noted recent development of National Spinal Radiofrequency Registry. • Clinicians should be caution about recommending repeat radiofrequency denervation until longer term effectiveness data becomes available. • No reliable clinical features/physical signs of facet joint pain. Features may include: increased pain unilaterally/bilaterally on lumbar paraspinal palpation. <ul style="list-style-type: none"> ○ Increased back pain on 1 or more of the following: extension (more than flexion), rotation, extension/side flexion, extension/rotation. And ○ No radicular symptoms And ○ No sacroiliac joint pain elicited using a provocation test. <p><u>NICE Recommendations</u></p> <ul style="list-style-type: none"> • Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when: <ul style="list-style-type: none"> ○ 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 localized back pain (rated as ≥ 5 on VAS or equivalent) at the time of the referral. • Only perform radiofrequency denervation in people with chronic low back pain after a positive response to a diagnostic medial branch block. 		<ul style="list-style-type: none"> • Substantial anticoagulation is a relative exclusion: temporary stop or covering anticoagulation. • Patient unwilling/lack of cooperation or unable to tolerate the procedure. • No repeat radiofrequency denervation should be considered if the benefit is for less than 16 months (NICE NH59 cost effectiveness). <p>Possible confounding factors: previous surgery, problems with previous injections.</p> <p>If diagnostic block carried out by a different clinician to the clinician performing radiofrequency, the radiological finding, volume and type of injection used and the patient pain diary should be sent with the referral.</p> <p>Diagnostic medial branch of the posterior primary ramus nerve blocks with 1ml or less of local anaesthetic at each level (no steroids) are recommended a diagnostic test before any destructive lesioning.</p> <p>There may be sustained benefit from diagnostic local anaesthetic blocks especially when they are administered in the context of multidisciplinary rehabilitation, which is strongly recommended.</p> <p>Radiofrequency denervation of the medial branch nerves produces a</p>
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			<p>more prolonged analgesic effect but this must be balanced against the potential for more significant complications.</p> <p>Measurement point for quality standard and outcome, PROMS: EQ5D, ODI, VAS before and 4-8 weeks, 6 months, 1 and 2years.</p> <p>Patients should be seen within 2 weeks of referral.</p>
Disc replacement	<p>Indications and rationale similar to that of spinal fusion. Procedure involves replacing intervertebral units with artificial discs that can act as a functional prosthetic replacement. Pain relief stems from removal of the painful disc. Single/multiple discs can be replaced during the same surgery. Some clinicians consider the advantage of disc arthroplasty over spinal fusion is that it preserves movement.</p> <ul style="list-style-type: none"> • 5 RCTs, 2 of which published as multiple papers. • 2 cohort studies. • 1 Cochrane review identified but not included. • 2 economic evaluations. <p><u>Disc replacement vs spinal fusion</u></p> <ul style="list-style-type: none"> • Clinical benefit of disc replacement for QoL (mental component) at short and long term but not for physical component. • 2 studies – no clinical difference between disc replacement and spinal fusion for pain or function at both short and long term. • 1 study showed greater numbers of adverse events for disc replacement < 4months. • No clinical difference between the 2 procedures for the reoperation outcome at 2 years (2 studies, low to very low quality). 	<p>The UK guidelines recommend that patients do not have disc replacement or spinal fusion surgery for low back pain, and instead recommend offering fusion surgery only as part of a randomized trial.</p>	<p>Do not refer for spinal fusion or disc replacement, NICE 2016.</p> <p>Total disc replacement is not permitted.</p>

	<p><u>Disc replacement vs 3-MBR</u></p> <ul style="list-style-type: none"> 1 study – clinically important benefit of disc replacement for QoL (physical component) in long term but not demonstrated for mental component. Although, concern around serious adverse outcomes of disc replacement surgery, in particular, 1 lower leg amputation and 4 cases of considerable blood loss out of 80 participants. This is a high occurrence of adverse events in a study not powered to detect harm and this is reflective of the risk observed in practice. <p><u>Economic</u></p> <ul style="list-style-type: none"> 1 cost utility analysis found that total disc replacement was dominant (less costly and more effective) compared to spinal fusion. 1 cost utility analysis found that total disc replacement was cost effective compared to 3 element MBR (ICER: £9544 per QALY gained). <p><u>Key Points</u></p> <ul style="list-style-type: none"> Concern about high number of severe adverse events associated with disc replacement in comparison to spinal fusion. High complexity of revision disc replacement procedures in patients, resulting in surgeons applying a much higher threshold for carrying out reoperations. Noted that comparison between disc replacement and 3 element MBR would be inappropriate as people with low back pain would often take part in an MBR programme before undergoing surgery. Some signs of benefit from disc replacement compared to other interventions but evidence very limited and not consistent across outcomes. Also, risk of harm outweighed benefit. Concern about this as disc replacement usually performed in younger patients due to its motion benefits. Therefore, appropriate to recommend against this. <p><u>NICE Recommendations</u></p> <ul style="list-style-type: none"> Do not offer disc replacement in people with low back pain. 		
Spinal cord stimulation	n/a Available in NICE (October 2018) Spinal cord stimulation for	Other passive electrical or physical modalities,	Currently the mean time for neuropathic pain to receiving a

	<p>chronic pain of neuropathic or ischaemic origin. Reviewed in November 2013.</p>	<p>such as ultrasound, transcutaneous electrical nerve stimulation traction, interferential therapy, short-wave diathermy, and back supports are generally ineffective and not recommended.</p>	<p>spinal cord stimulator is seven years. This time frame should be much shorter. This would prevent suffering and reduce ineffective therapies such as reoperation, repeat injections, medications and physical therapies.</p> <p>Referral for consideration of spinal cord stimulation:</p> <ul style="list-style-type: none"> • Chronic radicular, neuropathic pain as judged by: history, clinical examination and sometimes supported by investigation such as nerve conduction studies and quantitative sensory testing • Chronic mixed/spinal and radicular pain • Recurrence of pain or a failure of pain relief from anatomically successful spinal surgery. • Pain persistent for >6 months. • Insufficient benefit from a reasonable algorithm or evidence based usual care. <ul style="list-style-type: none"> ○ Anti-neuropathic pain pathway, x ray guided nerve root and epidural therapies, patient education, physical therapy • Patient accepts they have a long term chronic condition. • Patient has cognitive ability to manage the therapy long term. <p>Exclusions:</p> <ul style="list-style-type: none"> ○ Pregnancy at time of implant ○ Patient does not wish to have implantable device ○ Anticoagulant therapy where it is
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			<p>too dangerous to either stop or bridge to LMWH.</p> <ul style="list-style-type: none"> ○ Uncontrolled coagulopathy ○ Multiple co-morbidity likely to result in a poor functional outcome ○ Known allergy to titanium, steel or silicone. <p>Patient assessment recommended by MDT assessment, including Pain medical specialist, Pain Psychologist and Physiotherapist and specialist neuromodulation nurse.</p>
Acupuncture	Do not offer acupuncture for managing low back pain with or without sciatica.	<ul style="list-style-type: none"> • Acute low back pain (<6 weeks) – second line or adjunctive treatment. • Persistent low back pain (>12 weeks) - second line or adjunctive treatment. 	<p>For managing low back pain with or without sciatica, NICE 2016 recommended against acupuncture.</p> <p>Do not refer for acupuncture.</p> <p>Do not offer acupuncture.</p> <p>To decommission treatments which are recommended against by NICE 2016, such as acupuncture.</p>

Appendix 2 – Existing CCG Policies in London and

WELC (City & Hackney, Newham, Tower Hamlets and Waltham Forest) and SEL (Bexley, Bromley, Greenwich, Lambeth, Lewisham, Southwark) did not have a policy for interventional treatments for back pain at the time of this review.

NEL	NCL	SWL	NWL	London Choosing Wisely
BHR	NCP Pod			
Barking Havering Redbridge	Barnet Camden Enfield Haringey Islington	Croydon Kingston Merton Richmond Sutton Wandsworth	Brent Central Ealing Hammersmith & Fulham Harrow Hillingdon Hounslow West London	
Latest policy 2018	Latest policy 2015-16	Latest policy 2017-18		May 2018
<p>Spinal injections</p> <ul style="list-style-type: none"> injections to the intervertebral discs facet joint injections epidural injections for spinal claudication <p>Above are not routinely funded</p> <p>(BHR CCGs do routinely fund Medial branch blocks, Medial branch radiofrequency lesioning and Transforaminal epidural steroid injection/dorsal root ganglion pulsed radiofrequency)</p>	<p>Back surgery - interlaminar, transforaminal and caudal epidural injections for patients with radicular pain: This procedure is not routinely funded by the NCL CCGs and will only be considered for funding if the criteria below are met and evidenced.</p> <p>NCL CCGs will fund interlaminar, transforaminal and caudal epidural injections for patients with radicular pain due to herniated disc (where progressive neurological changes and/or impending caudaequina syndrome have been excluded) when the</p>	<p>Acupuncture for low back pain: not routinely funded</p> <p>Discectomy for low back pain: not routinely funded</p> <p>Back pain injections (facet joints, medial branch block, radiofrequency denervation)</p> <p>Malignancy If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service. See NICE Clinical Guideline 27: Referral Guidelines for Suspected Cancer (NICE 2005). Available at: http://www.nice.org.uk/guidance/CG27</p>	<p>NWL CCGs do NOT commission the following for low back pain and non-radicular spinal pain: a. Facet joint injections b. Therapeutic medial branch blocks c. Intradiscal therapy d. Prolotherapy e. Trigger point injections with any agent, including botulinum toxin f. Epidural steroid injections for chronic low back pain or for neurogenic claudication in patients with central spinal canal stenosis g.</p> <p>2. NWL CCGs fund epidurals (local anaesthetic and steroid) only in patients who have less than three months history of acute and severe lumbar radiculopathy at</p>	<p>This policy relates to interventional treatments for back pain only, as described in detail below.</p> <p>The following exclusions apply:</p> <ul style="list-style-type: none"> Children. Patients thought to have/have cancer (including metastatic spinal cord compression). Patients with neurological deficit (spinal cord compression or cauda equina symptoms), fracture or infection. <p>In ordinary circumstances, funding for interventional treatments for back pain is available for patients who</p>

	<p>following criteria have been met.</p> <p>Criteria for eligibility</p> <ol style="list-style-type: none"> 1. The patient is 16 years or above <p>AND</p> <ol style="list-style-type: none"> 2. The patient has radicular pain (below the knee for lower lumbar herniations, into the anterior thigh for upper lumbar herniations) consistent with the level of spinal involvement <p>OR</p> <ol style="list-style-type: none"> 3. There is evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise – positive up to 45° or positive femoral tension sign) <p>AND</p> <ol style="list-style-type: none"> 4. Symptoms persist for at least six weeks despite non-operative treatments (e.g. analgesia, advice and reassurance and manual therapy e.g. physiotherapy) <p>OR</p> <ol style="list-style-type: none"> 5. Uncontrolled pain resistant to normal analgesia regimes. <p>Epidural injections beyond the first three injections are provided as part of a comprehensive pain management programme provided there has been >50% reduction in symptoms for six weeks.</p>	<p>Clinical threshold</p> <p>SWL CCGs fund this procedure when all of the following criteria are met in Group 1, 2, 3 or 4.</p> <p>Group 1: Diagnostic facet joint injections: criteria (1 - 4) must be met.</p> <ol style="list-style-type: none"> 1. Patient is 18 or over at the time of application. <p>AND</p> <ol style="list-style-type: none"> 2. Patient has been assessed for surgical management of chronic spinal pain which has lasted more than 24 months without a diagnosis of the cause <p>NB. Date of patients first presented with chronic spinal pain date will need to be provided on the Tickbox form.</p> <p>AND</p> <ol style="list-style-type: none"> 3. All conservative management options have been tried and failed (e.g. exercise, pharmacotherapy including analgesia and muscle relaxants). <p>AND</p> <ol style="list-style-type: none"> 4. Patient shows an awareness that managing their condition requires making lifestyle changes. <p>Group 2: Medial Branch Block: criteria 5 must be met.</p>	<p>time of referral.</p> <ol style="list-style-type: none"> 3. NWL CCGs will NOT fund Spinal fusion or lumbar disc replacement for low back pain. Surgical procedures for specific causes of LBP e.g. spondylolisthesis, scoliosis or severe structural disease are routinely funded where clinical indicated. <ol style="list-style-type: none"> 4. NWL CCGs recommend that imaging should not routinely be offered in a non-specialist setting for people with low back pain with or without sciatica <p>Funding may be considered through the Individual Funding Request Route (IFR) in exceptional clinical circumstances</p> <p>Please note that there are dedicated policies for Acupuncture and Radiofrequency Denervation</p>	<p>meet the following criteria</p> <p>If the clinician considers the need for treatment on clinical grounds outside of these criteria, please refer to the CCG's Individual Funding Request policy for further information.</p> <p>This policy relates to adults over 16 years.</p> <p>Epidurals</p> <p>The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement</p> <p>AND</p> <p>The patient has moderate-severe symptoms that have persisted for 12 weeks or more (earlier if there are motor symptoms or there is no access to MRI)</p> <p>AND</p> <p>The patient has shown no sign of improvement despite conventional therapy of advice, reassurance, analgesia and manual therapy</p> <p>AND/OR</p> <p>The MRI scan (unless contraindicated) shows pathology concordant with the clinical diagnosis.</p> <p>A maximum of 3 epidural injections will be permitted, with evidence based on the following response rates:</p>
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	<p>• Patients may receive up to six injections six months apart provided there has been >50% reduction in symptoms for six weeks from each injection.</p> <p>Back surgery - therapeutic facet joint injections: This procedure is not routinely funded by the NCL CCGs and will only be considered for funding if the criteria below are met and evidenced.</p> <p>NCL CCGs will fund medial branch blocks for the management of cervical, thoracic and lumbar back pain as specified below. Criteria for eligibility NCL CCGs will fund medial branch blocks when all the following criteria are met:</p> <ol style="list-style-type: none"> 1. The pain has lasted for more than one year <p>AND</p> <ol style="list-style-type: none"> 2. The pain has resulted in moderate to significant impact on daily functioning <p>AND</p> <ol style="list-style-type: none"> 3. All conservative management options (advice and reassurance, analgesia and manual therapy e.g. physiotherapy) have been tried and failed. <p>Clinical practice Please provide documented evidence relating to:</p>	<p>5. Patient requires therapeutic testing prior to undergoing radiofrequency denervation.</p> <p>Group 3: First Radiofrequency Denervation: criteria (6-8) must be met.</p> <p>6. Patient's main source of pain is thought to come from structures supplied by the medial branch nerve and this is confirmed by a positive response to a diagnostic median nerve block in a suspected facet joint pain lasting more than 24 months NB: Positive response is expected to be 75 to 100% pain relief.</p> <p>AND</p> <p>7. Patient has pain that is greater than 5 on VAS scale or equivalent at the time of the application NB. Patient's VAS score will need to be provided on the Tickbox form.</p> <p>AND</p> <p>8. All conservative management options have been tried and failed (exercise, pharmacotherapy including analgesia and muscle relaxants).</p> <p>Group 4: Second or Third Radiofrequency Denervation: criteria (9 - 13) must be met.</p>		<ul style="list-style-type: none"> • 30% improvement after the first injection • 50% improvement after the second injection <p>For patients with persisting symptoms after 3 injections, re-approval of treatment with epidural injections will be needed through the IFR panel. This may be older/frailer patients who derive medium term benefit but are unsuitable or unwilling to have surgery.</p> <p><u>Spinal decompression</u> The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of spinal involvement AND The MRI scan (unless contraindicated) shows one or more areas of spinal stenosis whereby the pathology is concordant with the clinical diagnosis. AND The patient has shown no sign of improvement despite conventional therapy for 1 year.</p> <p><u>Discectomy</u> The patient has spinal pain associated with radicular pain/myotomal pain consistent with the level of</p>
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	<p>In the diagnostic phase the patient may receive up to one injection, in the therapeutic phase, up to two injections six months apart provided there has been</p> <ul style="list-style-type: none"> • >50% reduction in symptoms for six weeks. • Medial branch blocks beyond the first three injections should be provided as part of a comprehensive pain management programme. • Intra-articular facet joint injections will not normally be funded unless it forms part of a pre-operative workup, including imaging. <p>Back surgery - thermal radiofrequency denervation (lumbar and cervical facet joints)</p> <p>This procedure is not routinely funded by the NCL CCGs and will only be considered for funding if the criteria below are met and evidenced.</p> <p>Criteria for eligibility NCL CCGs will fund thermal radiofrequency controlled denervation of the medial branch of the dorsal rami of the lumbar and cervical facet joints (medial branch neurotomy) in the following</p>	<p>9. Patient had the last radiofrequency denervation at least 12 months before this planned procedure. AND</p> <p>10. Patient had a positive response to the previous radiofrequency denervation as evidenced by VAS scale NB. Patient's VAS scores pre and post procedure will need to be provided on the Tickbox form. AND</p> <p>11. Patient had a positive response to the previous radiofrequency denervation as evidenced by an improvement in the EQ-5D scores. AND</p> <p>12. Patient had a reduction in medication taken at three months following the previous radiofrequency denervation. AND</p> <p>13. Patient had no more than two previous radiofrequency denervation. Please note: SWL CCGs do not routinely fund</p> <ul style="list-style-type: none"> • Facet joint injections and medial branch block for any therapeutic indications • More than three radiofrequency denervation injections for patients. 		<p>spinal involvement AND</p> <p>The patient has shown no sign of improvement despite conventional therapy for 12 weeks AND</p> <p>Patients have acute, severe and unremitting sciatica concordant with disc herniation demonstrated on MRI scan within 12 weeks (unless contraindicated).</p> <p><u>Radiofrequency Denervation (including non-anterior radicular cervical, thoracic and lumbar areas)</u></p> <p>Patient has persistent pain AND</p> <p>Conservative management including physiotherapy and multidisciplinary input has failed to achieve meaningful relief of pain AND</p> <p>MRI or SPECT (unless contraindicated) findings are concordant with the patient's symptoms and other structural lesions are excluded AND</p> <p>The patient has had an 80% improvement in pain from a diagnostic medial branch block, which is clearly documented in the patient's notes.</p>
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	<p>circumstances:</p> <ol style="list-style-type: none"> 1. Patients aged over 16 AND 2. Non-radicular lumbar (all levels) or cervical (C3-4 and below) facet joint pain AND 3. All conservative management options (advice and reassurance, analgesia and manual therapy e.g. physiotherapy) have been tried and failed AND 4. Radiological imaging to rule out any correctable structural lesion e.g. MRI AND 5. At least two anaesthetic diagnostic blocks one of which must be of the medial branch of the dorsal ramus innervating the target facet joint with at least 50% reduction in pain following each block during the activities that normally generate pain. The pain relief must be consistent with the expected duration of the anaesthetic block AND 6. All procedures must be performed under fluoroscopy (x-ray guidance). <p>Thermal radiofrequency denervation is provided as part of a comprehensive</p>	<p>Epidural injections for low back pain: Malignancy If there is any suspicion of malignancy, patients should be referred immediately to the appropriate service. See NICE Clinical Guideline 27: Referral Guidelines for Suspected Cancer (NICE 2005). Available at: http://www.nice.org.uk/guidance/CG27</p> <p>Clinical threshold SWL CCGs fund this procedure when all of the following criteria are met in Group 1 or 2. Group 1: First Injections criteria (1 – 4) must be met. 1. Patient is 18 or over at the time of application NB. Children for complex pain management should receive their care at a specialist centre, which is commissioned by NHS England. AND 2. Patient has a) Radicular pain consistent with the level of spinal involvement (below the knee for lower lumbar herniation, into the anterior thigh for upper lumbar herniation) OR b) Nerve-root irritation with</p>		<p>The patient should have one diagnostic medial branch block followed by one therapeutic radiofrequency denervation procedure. If further treatment is required through radiofrequency denervation, approval should be sought through the IFR panel.</p> <p><u>Diagnostic Spinal injections (including facet joint injections, medial branch blocks and sacroiliac joint injections)</u> Patient is under the care of a specialist</p> <p>The patient may have up to two diagnostic spinal injections (if both short and long acting injections are being used) within a two-week period. The second diagnostic spinal injection may only be given if the first elicits 80% improvement in pain and this is clearly documented in the notes.</p> <p><u>Therapeutic Spinal injections (including facet joint injections, medical branch blocks, intradiscal therapy, prolotherapy, trigger point injections, sacroiliac joint injections)</u> Spinal injections are not routinely funded.</p>
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	<p>pain management programme.</p> <ul style="list-style-type: none"> • NCL CCGs will not fund cryoneurolysis or laser denervation. • NCL CCGs will fund up to three facet denervations on one occasion. • NCL CCGs will not fund re-treatment at the same location unless at least six months have elapsed since prior treatment. 	<p>a positive nerve-root tension sign (straight leg raise–positive between 30° and 70° or positive femoral tension sign).</p> <p>AND</p> <p>3. All conservative management options have been tried and failed within the last 12 months (physiotherapy treatments and guided exercise programmes where a patient is able to participate, pharmacotherapy including analgesia and muscle relaxants)</p> <p>NB. This should be provided via comprehensive pain management services where it is available.</p> <p>AND</p> <p>4. Patient suffers from moderate to severe low back pain for more than 12 months as measured by a recognised pain scale* (where comprehensive pain management service is not accessible, then the period of conservative treatment should be 6 months)</p> <p>NB. Date of patients first presented with low back pain date will need to be provided on the Tickbox form.</p> <p>Group 2: Repeat Injections Criteria 5 and 6 must be met. Patients may receive a</p>		<p><u>Spinal Fusion</u> Spinal fusion surgery is not routinely funded for non-radicular back pain.</p> <p><u>Lumbar Disc Replacement</u> Lumbar disc replacement surgery is not routinely funded.</p> <p><u>Acupuncture</u> Acupuncture for back pain is not routinely funded.</p> <p><u>Ozone Discectomy</u> Ozone discectomy is not routinely funded.</p> <p><u>Epidural Lysis</u> Epidural lysis is not routinely funded.</p>
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		<p>maximum of 2 injections within a 12 month period.</p> <p>5. Patient had a positive response to the last epidural injection as measured by a recognised pain scale* (Positive response is expected to be 75 to 100% pain relief)</p> <p>NB. Patient's VAS scores pre and post procedure will need to be provided on the Tickbox form.</p> <p>AND</p> <p>6. Patient had a positive response to the last epidural injection resulting in improved functioning.</p> <p>* The following tools are recognised by NICE to be used as pain scales</p> <ul style="list-style-type: none"> • Brief Pain Inventory (BPI) • Roland Morris Disability Questionnaire (RMDQ) • Visual Analogue Pain Scale (VAS). <p>Please note:</p> <ul style="list-style-type: none"> • Injections MUST be carried out under radiological guidance. • Patients may receive a maximum of two injections within a 12 month period. 		
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Appendix 3 – Proposed OPCS & ICD 10 Codes

OPCS Codes (Procedure codes)	
A521	Therapeutic lumbar epidural injection
A522	Therapeutic sacral epidural injection
A528	Other specified therapeutic epidural injection
A529	Unspecified therapeutic epidural injection
A572	Rhizotomy of spinal nerve root
A573	Radiofrequency controlled thermal destruction of spinal nerve root
A577	Injection of therapeutic substance around spinal nerve root
V251	Primary extended decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V252	Primary extended decompression of lumbar spine NEC
V253	Primary posterior decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V254	Primary posterior laminectomy decompression of lumbar spine
V255	Primary posterior decompression of lumbar spine NEC
V256	Primary lateral foraminotomy of lumbar spine
V257	Primary anterior corpectomy of lumbar spine and reconstruction HFQ
V258	Other specified primary decompression operations on lumbar spine
V259	Unspecified primary decompression operations on lumbar spine
V261	Revisional extended decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V262	Revisional extended decompression of lumbar spine NEC
V263	Revisional posterior decompression of lumbar spine and intertransverse fusion of joint of lumbar spine
V264	Revisional posterior laminectomy decompression of lumbar spine
V265	Revisional posterior decompression of lumbar spine NEC
V266	Revisional lateral foraminotomy of lumbar spine
V267	Revisional anterior corpectomy of lumbar spine and reconstruction HFQ
V268	Other specified revisional decompression operations on lumbar spine
V269	Unspecified revisional decompression operations on lumbar spine
V281	Primary insertion of lumbar interspinous process spacer
V282	Revisional insertion of lumbar interspinous process spacer
V288	Other specified insertion of lumbar interspinous process spacer
V289	Unspecified insertion of lumbar interspinous process spacer
V331	Primary laminectomy excision of lumbar intervertebral disc
V332	Primary fenestration excision of lumbar intervertebral disc
V333	Primary anterior excision of lumbar intervertebral disc and interbody fusion of joint of lumbar spine
V334	Primary anterior excision of lumbar intervertebral disc NEC
V335	Primary anterior excision of lumbar intervertebral disc and posterior graft fusion of joint of lumbar spine
V336	Primary anterior excision of lumbar intervertebral disc and posterior instrumentation of lumbar spine
V337	Primary microdiscectomy of lumbar intervertebral disc
V338	Other specified primary excision of lumbar intervertebral disc
V339	Unspecified primary excision of lumbar intervertebral disc

V341	Revisional laminectomy excision of lumbar intervertebral disc
V342	Revisional fenestration excision of lumbar intervertebral disc
V343	Revisional anterior excision of lumbar intervertebral disc and interbody fusion of joint of lumbar spine
V344	Revisional anterior excision of lumbar intervertebral disc NEC
V345	Revisional anterior excision of lumbar intervertebral disc and posterior graft fusion of joint of lumbar spine
V346	Revisional anterior excision of lumbar intervertebral disc and posterior instrumentation of lumbar spine
V347	Revisional microdiscectomy of lumbar intervertebral disc
V348	Other specified revisional excision of lumbar intervertebral disc
V349	Unspecified revisional excision of lumbar intervertebral disc
V351	Primary excision of intervertebral disc NEC
V352	Revisional excision of intervertebral disc NEC
V358	Other specified excision of unspecified intervertebral disc
V359	Unspecified excision of unspecified intervertebral disc
V363	Prosthetic replacement of lumbar intervertebral disc
V382	Primary posterior interlaminar fusion of joint of lumbar spine
V383	Primary posterior fusion of joint of lumbar spine NEC
V384	Primary intertransverse fusion of joint of lumbar spine NEC
V385	Primary posterior interbody fusion of joint of lumbar spine
V386	Primary transforaminal interbody fusion of joint of lumbar spine
V388	Other specified primary fusion of other joint of spine
V389	Unspecified primary fusion of other joint of spine
V393	Revisional posterior interlaminar fusion of joint of lumbar spine
V394	Revisional posterior fusion of joint of lumbar spine NEC
V395	Revisional intertransverse fusion of joint of lumbar spine NEC
V396	Revisional posterior interbody fusion of joint of lumbar spine
V397	Revisional transforaminal interbody fusion of joint of lumbar spine
V398	Other specified revisional fusion of joint of spine
V399	Unspecified revisional fusion of joint of spine
V404	Posterior instrumented fusion of lumbar spine NEC
V411	Posterior attachment of correctional instrument to spine
V418	Other specified instrumental correction of deformity of spine
V433	Excision of lesion of lumbar vertebra
V473	Biopsy of lumbar vertebra
V481	Radiofrequency controlled thermal denervation of spinal facet joint of cervical vertebra
V485	Radiofrequency controlled thermal denervation of spinal facet joint of lumbar vertebra
V486	Denervation of spinal facet joint of lumbar vertebra NEC
V487	Radiofrequency controlled thermal denervation of spinal facet joint of vertebra NEC
V488	Other specified denervation of spinal facet joint of vertebra
V489	Unspecified denervation of spinal facet joint of vertebra
V493	Exploratory lumbar laminectomy
V508	Other specified manipulation of spine
V509	Unspecified manipulation of spine
V544	Injection around spinal facet of spine

V583	Primary automated percutaneous mechanical excision of lumbar intervertebral disc
V588	Other specified primary automated percutaneous mechanical excision of intervertebral disc
V598	Other specified revisional automated percutaneous mechanical excision of intervertebral disc
V603	Primary percutaneous decompression using coblation to lumbar intervertebral disc
V613	Revisional percutaneous decompression using coblation to lumbar intervertebral disc
V671	Primary posterior lumbar medial facetectomy
V672	Primary hemilaminectomy decompression of lumbar spine
V678	Other specified other primary decompression operations on lumbar spine
V679	Unspecified other primary decompression operations on lumbar spine
V681	Revisional posterior lumbar medial facetectomy
V682	Revisional hemilaminectomy decompression of lumbar spine
V688	Other specified other revisional decompression operations on lumbar spine
V689	Unspecified other revisional decompression operations on lumbar spine
W903	Injection of therapeutic substance into joint
X306	Injection of anaesthetic agent NEC
X308	Other specified injection of therapeutic substance
X309	Unspecified injection of therapeutic substance
Z063	Lumbar spinal cord
Z064	Meninges of spinal cord
Z068	Specified spinal cord NEC
Z069	Spinal cord NEC
Z073	Spinal nerve root of lumbar spine

With the following ICD-10 diagnosis code(s): (to be confirmed)

S39.01 2	Low back strain
M51.0	Lumbar and other intervertebral disc disorders with myelopathy
M51.1	Radiculopathy – lumbar and other intervertebral disc disorder
M51.2	lumbago due to intervertebral disc displacement
M51.3	Other specified intervertebral disc degeneration
M54.3	Sciatica
M54.4	lumbago with sciatica
M54.9	Dorsalgia
M55.5	low back pain
G54.4	Lumbosacral root disorders, not elsewhere specified
G54.1	Lumbosacral plexus disorders
G55.1	Nerve root and plexus compressions in intervertebral disc disorders

Appendix 4 – Additional evidence review following first Task & Finish Group

Ozone Discectomy

Emerging evidence on the potential role of ozone injection as another intervention for radicular pain was highlighted by one of the Task & Finish group members, who later provided references and abstracts from 36 studies over a 15 year period between 2003 and 2018. All abstracts were read in order to identify which papers might be most helpful in relation to this policy. Many of the earliest abstracts reported on research to explore the role of ozone injections as a novel approach for radicular pain. Several studies focussed on details of how best to radiologically image the siting of or results of injections, whilst others focussed on the impact of using different doses of ozone, or the impact of ozone in different patient cohorts. After this detailed scrutiny, the seven abstracts and papers reviewed in more detail below included a meta-analysis in 2010 of earlier studies and papers that focussed on the mechanisms of action of ozone, and issues of patient selection and technique, published between 2014 and 2017.

Ozone discectomy involves an injection of ozone (gas) in and around the disc. The studies below involve using this injection for radicular pain only^{1,2} and suggest that it is not suitable for non-specific low back pain. The studies reviewed demonstrate a potentially effective use of ozone discectomy for specific patients, whom have tried and failed to manage their pain with conservative treatment^{1,3-5}. A prospective cohort study combined ozone discectomy with automated percutaneous lumbar discectomy (spinal procedure whereby a volume of the nucleus pulposus of the herniated disc is aspirated), named ALPD, and compared it with caudal epidural injections. It found statistically significant differences between the groups at 1 and 6 months follow-up, demonstrating the superiority of APLD against caudal epidural injections. However, this study had limitations with bias due to the methodology and design.⁶

The 2010 meta-analysis (of 12 studies) suggests that oxygen/ozone treatment of herniated discs is “effective and extremely safe procedure”. It concluded that pain and function outcomes were similar to those for lumbar discs treated with surgical discectomy, however, with a much lower complication rate of <0.1%.⁵

From the studies reviewed, there is a lack of high quality randomised controlled trials to qualify the use of ozone discectomy and therefore insufficient evidence for its routine use at this time. Relevant text from the evidence/abstract has been highlighted below.

1	Other	Interventional Radiology	Muto M <i>et al.</i> Rational approach, technique and selection criteria treating lumbar disc herniations by oxygen-ozone therapy. <i>Interventional Radiology</i> 2016;22(6):736-740 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5564357/	Abstract Radicular lumbar back pain is an important public health problem not yet benefiting from a unequivocal treatment approach. Medical and physical therapies represent the first solution; however, when these fail, the second therapeutic step is still controversial and mini-invasive treatments may play an important role. In these cases oxygen-ozone therapy has been proved to be a very safe and effective option that is widely used with different modalities. This paper, by reviewing oxygen-ozone therapy literature data, aims to describe the rationale of oxygen-ozone therapy for the treatment of lumbar disk herniations, propose an effective procedural technique and clarify patient selection criteria; furthermore, complications and follow-up management are also considered.
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				<p><u>Relevant Key Points from Study</u></p> <ul style="list-style-type: none"> • The natural history of disc herniation tends to be favourable. Spontaneous regression of disc herniation is seen in two-thirds of cases and a spontaneous resolution of pain within the acute phase (from six to 12 weeks after pain onset) in 60–80% of patients. Nevertheless, the one-year recurrence rate is significant and approximately 37–54% of patients retain the pain after long periods of time (at least 12 months) • Oxygen–ozone gas mixture (O₂O₃) is commonly used in clinical practice, mostly in Europe and Asia, in the treatment of nociceptive-neuropathic pain, in inflammatory and degenerative processes of the muscle-skeletal system and especially in degenerative disc disease and disc herniation • Biological action not fully understood but some mechanisms of action proposed: reduction of inflammatory components, hyper-oxygenation of the area of interest, diminishing the size of the herniation, simulation of the repair process. • The main objective in patient evaluation is to identify the source of the pain by acquiring a complete history and performing a physical examination, supplemented with appropriate imaging studies. It must be ensured that a conservative approach has already been tried with pharmacological and physical therapy for at least 4–6 weeks. • The best clinical indications for O₂O₃ are radicular pain rather than low back pain; the patient must refer pain in a well-discriminated and constant cutaneous dermatome with positive Lasègue test; the pain should score 5 or more on the visual analogue scale (VAS) • If a facet syndrome is supposed, a facet infiltration with steroid and local anaesthetic is suggested as diagnostic test before O₂O₃ treatment • The clinical evaluation must be in accordance with imaging studies, which must demonstrate lumbar herniation/protrusion congruent with the clinical symptoms; significant structural deformity of spine, severe vertebral osteoarthritis, fractures or calcified hernia should not be present. • Recently, some studies referred poor improvement of clinical symptoms if magnetic resonance (MR) diffusion weighted imaging (DWI) prior to the treatment shows a decreased Apparent Diffusion Coefficient index (ADC) of
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				<p>the disc; this index is related to the content of water of the tissues.</p> <ul style="list-style-type: none"> • It is important to acknowledge that imaging by itself is not a sufficient indication to treatment, taking into account that disc bulging is present in 52% of the population and disc herniation is present in around 20–28% of asymptomatic subjects. • There should not be a neurological motor deficit, or cauda equina syndrome. Suspected infectious/inflammatory or neoplastic bone lesions must be excluded. In these cases O₂O₃ is completely ineffective • Absolute contra-indication to the procedure is referred allergy to proposed drugs. Relative contra-indications to the procedure are: bleeding disorder, pregnancy, G6PD deficiency, hyperthyroidism, severe anaemia, severe myasthenia, recent myocardial infarction and history of mental disease. • Although the treatment with O₂O₃ has many advantages, the patient's selection criteria are the key points to a successful clinical result. • Ozone therapy for lumbar disc herniation is a procedure with very low or no adverse effects with concentrations of 10–40 µg/ml. Most of the studies report no complications, the overall complications rate being estimated at under 0.1% • In the appropriate clinical/imaging context, intradiscal injection of O₂O₃ has a reported success rate that reaches 90% at short-term follow-up (six months) and a 75–82% success rate at long-term follow-up (12 months) with no major or minor side effects. Around 73% of the patients who went through O₂O₃ therapy are still better at five and 10 years. An average reduction in pain intensity in VAS from 7.58 before treatment to 2.64 two years after treatment has been reported, with similar results in ODI classification • Finally, starting a physical rehabilitation programme is strongly recommended • O₂O₃ therapy is a safe and cost-effective approach for patients with sciatica refractive to conservative therapy, having demonstrated good short- and long-term results, significantly shorter recovery time compared with the alternative treatments, and reduction of the need for surgery. Moreover, it must be considered also that patients without a good response to O₂O₃ therapy may still undergo surgical discectomy
2			Muto M <i>et al.</i> Percutaneous treatment of herniated	Abstract

			<p>lumbar disc by intradiscal oxygen-ozone injection. <i>Interventional Radiology</i> 2008;4(4):279-86</p> <p>Full text unavailable</p>	<p>We report our experience of treating lumbar herniated disc by intradiscal injection of an oxygen-ozone mixture. Ozone (O₃, MW = 48) is a triatomic molecule, having antiviral, disinfectant and antiseptic properties. Several mechanisms of action have been proposed to explain the efficacy of the treatment: 1) analgesic action; 2) anti-inflammatory action; 3) oxidant action on the proteoglycan in the nucleus pulposus. We treated 93 patients (50 women, 43 men) aged from 24 to 45 yrs (average age 38 yrs) from June 1996 to April 1998. All patients presented sciatica and/or low back pain, lasting two or more months; patients had in the mean time received both medical and physical therapy with mild or no benefit. Diagnostic tests in all patients included plain film x-ray, CT and/or MR at the level of the lumbar spine disclosing a herniated or protruded disc with nerve root or thecal sac compression. We divided patients to be treated in to two groups: the first one group included 35 patients already selected for surgery who presented herniated or protruded disc with radicular pain with associated neurological deficit (hypoesthesia and partial loss of reflex). Those patients had already had medical and physical therapy for two or more months and agreed to try the percutaneous treatment before surgery. CT or MR in this group demonstrated the presence of intraforaminal, extra or subligamentary and sequestered herniated disc. The second group included 58 patients with radicular pain but without neurological deficit; patients in this group had received medical and/or physical therapy for two or more months and CT showed the presence of a small subligamentary herniated or protruded disc. We considered the results according to the modified MacNab method. In the first group we had "failure" in all patients; in seven cases the symptoms improved for one month, but recurred later on. In the second group 45 patients had "success" showing complete clinical recovery within five to six days after treatment, all remained without symptoms up to six months or more of follow-up. The remaining 13 patients presented the same symptoms again within three months after a temporary clinical recovery. The goal of this study was to present this new technique that can also be compared with a previous study of different percutaneous treatment. Clinical and neuroradiological indications and the contraindications are well known, and must be followed to achieve good results and avoid complications.</p>
3	Case-control Study	Medical Science Monitor	Tong N. <i>et al.</i> Therapeutic effect of medical ozone on lumbar disc herniation. <i>Medical Science Monitor</i>	<p>Background This study aimed to investigate the therapeutic effect of low,</p>

			2018;24:1962-9	<p>medium, and high concentrations of medical ozone on trauma-induced lumbar disc herniation.</p> <p>Material/Methods A total of 80 patients were included and were grouped into a control group, a low medical ozone (20 µg/ml) group, a medium medical ozone (40 µg/ml) group, and a high medical ozone (60 µg/ml) group. The CT scan and enzyme-linked immunosorbent assay (ELISA) were used to detect IL-6 level, SOD activity, IgM, and IgG levels upon admission and at 6 and 12 months after follow-up. The area under the ROC curve (AUC) was calculated for visual analogue scale (VAS) and efficiency rate.</p> <p>Results All patients showed disc retraction at 6- and 12-month follow-up; while patients in the medium medical ozone (40 µg/ml) group showed the greatest disc retraction rate. The IL-6, IgM, IgG, and VAS levels significantly decreased while SOD activity increased among all groups over time (p<0.05). The AUC_{IL-6}, AUC_{IgG}, AUC_{IgM}, and AUC_{SOD} was closest to 1 in the medium medical ozone (40 µg/ml) group compared with other groups (p<0.01), with the highest efficacy at 6 (35%) and 12 (85%) months during follow-up.</p> <p>Conclusions Low concentrations of medical ozone (20 µg/ml and 40 µg/ml) reduced the serum IL-6, IgG, and IgM expression, presenting as analgesic and anti-inflammatory effects, while high concentrations of medical ozone (60 µg/ml) increased the serum IL-6, IgG, IgM expression, presenting as pain and pro-inflammatory effects. The medical ozone concentration of 40 µg/ml showed the optimal treatment efficacy.</p>
4	Retrospective case control study	Interventional Radiology	<p>Bruno F <i>et al.</i> MRI findings in lumbar spine following O2-O3 chemiodiscolysis: A long-term follow-up. <i>Interventional Neuroradiology</i> 2017;23(4):444-450</p> <p>Full text unavailable</p>	<p>Abstract Intradiscal O2-O3 injections are conventionally used as a minimally invasive treatment for lumbar disc herniation in patients not responding to conservative treatments. The aim of the present study is to report data of long-term imaging follow-up (3 years) of patients treated with intradiscal O2-O3 lumbar chemiodiscolysis. We evaluated the changes of disc volume and the modifications in disc appearance (in terms of disc degeneration) and endplate changes (according to Modic), comparing the results with a control group of patients. Our results showed a stable reduction of the disc herniation volume in patients treated compared with the control group, while we did not find statistically significant differences in terms of disc degeneration and endplate changes (Modic). We concluded that the O2-O3 discolysis, despite leading to a significant shrinkage of the disc</p>

				herniation, does not involve - in the long term - biomechanical changes of the spine in terms of acceleration of the disc degeneration process in comparison with the natural course.
5	Meta-analysis		<p>Steppan J <i>et al.</i> A meta-analysis of the effectiveness and safety of ozone treatments for herniated lumbar discs. <i>Journal of Vascular Interventional Radiology</i> 2010;21(4):534-49</p> <p>Full text unavailable</p>	<p>Abstract PURPOSE: To determine statistically significant effects of oxygen/ozone treatment of herniated discs with respect to pain, function, and complication rate. MATERIALS AND METHODS: Random-effects metaanalyses were used to estimate outcomes for oxygen/ozone treatment of herniated discs. A literature search provided relevant studies that were weighted by a study quality score. Separate metaanalyses were performed for visual analog scale (VAS), Oswestry Disability Index (ODI), and modified MacNab outcome scales, as well as for complication rate. Institutional review board approval was not required for this retrospective analysis. RESULTS: Twelve studies were included in the metaanalyses. The inclusion/exclusion criteria, patient demographics, clinical trial rankings, treatment procedures, outcome measures, and complications are summarized. Metaanalyses were performed on the oxygen/ozone treatment results for almost 8,000 patients from multiple centers. The mean improvement was 3.9 for VAS and 25.7 for ODI. The likelihood of showing improvement on the modified MacNab scale was 79.7%. The means for the VAS and ODI outcomes are well above the minimum clinically important difference and the minimum (significant) detectable change. The likelihood of complications was 0.064%. CONCLUSIONS: Oxygen/ozone treatment of herniated discs is an effective and extremely safe procedure. The estimated improvement in pain and function is impressive in view of the broad inclusion criteria, which included patients ranging in age from 13 to 94 years with all types of disc herniations. Pain and function outcomes are similar to the outcomes for lumbar discs treated with surgical discectomy, but the complication rate is much lower (<0.1%) and the recovery time is significantly shorter.</p>
6	Prospective cohort study		Crockett MT <i>et al.</i> Ozone-augmented percutaneous discectomy: a novel treatment option for refractory discogenic sciatica. <i>Clinical Radiology</i> 2014;69(12):1280-6	<p>Abstract AIM: To assess the short and medium-term efficacy and safety of a novel, minimally invasive therapeutic option combining automated percutaneous lumbar discectomy, intradiscal ozone injection, and caudal epidural:</p>

			<p>https://www.clinicalradiologyonline.net/article/S0009-9260(14)00400-0/fulltext</p>	<p>ozoneaugmented percutaneous discectomy (OPLD). MATERIALS AND METHODS: One hundred and forty-seven patients with a clinical and radiological diagnosis of discogenic sciatica who were refractory to initial therapy were included. Fifty patients underwent OPLD whilst 97 underwent a further caudal epidural. Outcomes were evaluated using McNab's score, improvement in visual analogue score (VAS) pain score, and requirement for further intervention. Follow-up occurred at 1 and 6 months, and comparison was made between groups. RESULTS: OPLD achieved successful outcomes in almost three-quarters of patients in the short and medium term. OPLD achieved superior outcomes at 1 and 6 months compared to caudal epidural. There was a reduced requirement for further intervention in the OPLD group. No significant complications occurred in either group. DISCUSSION: OPLD is a safe and effective treatment for patients with refractory discogenic sciatica in the short and medium term. OPLD has the potential to offer an alternative second-line minimally invasive treatment option that could reduce the requirement for surgery in this patient cohort.</p> <p><u>Relevant Key Points from Study</u></p> <ul style="list-style-type: none"> • Ninety percent of cases of sciatica are associated with lumbar disc herniation usually occurring at the L4–5 or L5–S1 level • Majority of patients respond well to conservative treatments but approximately 10% require further intervention. • Surgery can produce satisfactory results in a high proportion of patients in the short to medium term. However, long-term studies have reported variable benefits with a high proportion of patients describing persistent pain • APLD aims to reduce mechanical nerve root compression by aspirating a volume of the nucleus pulposus of the herniated intervertebral disc using a percutaneously placed suction cutting probe. • Intradiscal ozone injection involves injection of ozone gas into the nucleus pulposus of the herniated disc leading to proteoglycan hydrolysis and subsequent partial fibrosis. This leads to a reduction in disc volume and relief of mechanical nerve root compression. In addition, diffusion of ozone into the surrounding tissues has direct anti-inflammatory and analgesic effects, inhibiting synthesis of pro-inflammatory mediators such
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				<p>as prostaglandins and bradykinins</p> <ul style="list-style-type: none"> • APLD and intra-discal ozone injection have demonstrated significant promise in the treatment of discogenic sciatica when administered individually • No prior study has attempted to assess a therapeutic option combining these modalities, which could utilize a multimodal approach to decompress the disc herniation whilst simultaneously reducing the associated cascade of inflammatory mediators • One hundred and forty-seven [85 men (58%) and 62 women (42%)] consecutive patients attending the minimally invasive back pain clinic • After being offered a choice of OPLD or caudal epidural alone, 50 patients chose to undergo OPLD and 97 chose to undergo caudal epidural alone • There was no significant difference between pre-procedure VAS sciatica symptom scores between the two groups when analysed using a two sample t-test. • OPLD: Seventy-two percent of patients treated with OPLD had a successful outcome at 1 month follow-up, and 68% had a successful outcome at 6 months follow-up • Of patients treated with caudal epidural alone, 62.8% had a successful outcome at 1 month follow-up and 51% had a successful outcome at 6 months follow-up • Statistically significant differences between the groups was achieved at both 1 and 6 months follow-up with the OPLD cohort achieving higher McNab scores and greater improvements in symptoms of sciatica as measured using VAS pain scores • No significant complications or side effects were reported in either of the treatment groups • These results compare favourably to studies assessing intra-discal ozone or APLD used individually.
7	Other	Journal of Vascular Interventional Radiology	<p>Murphy K <i>et al.</i> Percutaneous treatment of herniated lumbar discs with ozone: investigation of the mechanisms of action. <i>Journal of Vascular Interventional Radiology</i> 2016;27(8):1242-1250</p> <p>Full text unavailable</p>	<p>Abstract PURPOSE: To elucidate the mechanism of action of intradiscal oxygen-ozone therapy for herniated intervertebral disc therapy. METHODS: Ozone's mechanism of action was investigated using 3 approaches: mathematical models of intervertebral disc space to explore the relationship between disc pressure and volume; ozonolysis experiments using glycosaminoglycans (GAGs) from a Chinese hamster ovary cell line that were similar in composition to GAGs found in human nucleus pulposus; and experiments in which live Yucatan miniature</p>

				<p>pigs received various concentrations of percutaneous, image-guided intradiscal oxygen-ozone treatment and were examined (after sacrifice) with histology and semiquantitative analysis of disc cytokine concentrations.</p> <p>RESULTS: Engineering calculations support observations that a small (6%) disc volume reduction can result in considerable (9.84%) intradiscal pressure reduction. Porcine disc histology and Chinese hamster ovary GAG ozonolysis results showed that administered ozone reacted with and fragmented disc proteoglycans, reducing disc volume through disc dehydration. Cytokine analysis of porcine discs found that each of 4 cytokines measured (interleukin [IL]-1β, IL-6, IL-8, and tumor necrosis factor α) increased in concentration after 2 wt% ozone treatment.</p> <p>CONCLUSIONS: Oxygen-ozone therapy breaks down proteoglycan GAGs that maintain disc osmotic pressure, dehydrating the nucleus pulposus and reducing intervertebral disc volume. This is likely a primary mechanism by which ozone relieves nerve root compression and alleviates herniated disc-related pain. Additionally, 2 wt% ozone appears to interact with intradiscal cytokines, generating an antiinflammatory response that may contribute to symptom improvement.</p>
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Summarised West Suffolk Policy

- Patients with back pain secondary to spinal metastases are exempt from this policy, as it is felt that their clinical condition requires more prompt intervention. These patients will require an IPA (locally agreed).
- This policy does not apply to patients for whom a specialist MDT feel have significant comorbidities that would inhibit their ability to comply with rehabilitation and biopsychosocial pain management (locally agreed).
- Children aged under 18 years may have diagnostic injections if deemed appropriate by an MDT assessment, including both pain specialists and paediatricians. The patient must also meet the normal criteria detailed below (locally agreed).

West Suffolk CCG will fund controlled SI joint injections for the diagnosis of SI joint pain when all the following criteria are met:

The patient is part of a comprehensive pain management programme and all conservative management options (physiotherapy treatments and guided exercise programmes, pharmacotherapy including analgesia and muscle relaxants) have been tried and failed
AND

The patient is suffering with non-radicular low back with duration of pain of at least 3 months
AND

A MDT or a pain specialist or MSK Physician / GPSI (with back pain assessment, diagnostic and treatment skills) has assessed the patient and is of the opinion that a SI joint is the most likely cause of pain
AND

The pain has resulted in documented moderate to significant impact on daily functioning (a loss of physical function of 50% or greater)
AND

No evidence of contraindications is present for the needle placement and injection of local anaesthetics.

Repeat injections

1. Patients may receive up to 2 diagnostic SI joint injections 1 - 2 weeks apart. The second injection may only be given if the first elicits a positive response.

2. Injections are not approved other than for diagnosis.

3. A positive diagnosis is considered to be greater than 60% reduction in symptoms for at least 8 weeks (locally agreed)

4. Patients with a positive diagnosis may be considered for denervation treatment provided that:

- The patient has been reviewed by a pain specialist or MSK Physician / GPSI and there is continued engagement with self-care.
- The patient remains within a comprehensive pain management programme.

Denervations may be repeated – please refer to the commissioning statement for denervations.

This policy was derived using four references. In summary, the references cited by West Suffolk CCG do not specifically address the commissioning criteria set out above. The evidence used was of high quality, incorporating meta-analysis and prevalence data, and concludes that there is generally limited evidence for the use of therapeutic intraarticular and periarticular sacroiliac joint injections. However, despite limited evidence for intraarticular injections at present, the evidence base is emerging. Furthermore, the evidence suggested there was no single best diagnostic test, other than a diagnostic block for sacroiliac joint pain. Relevant text from the evidence/abstract has been highlighted below.

Level of evidence	Source	Citation	Summary
Other	Map of Medicine	The Map of Medicine and the British Pain Society. Low Back and Radicular Pain. England View. London: Map of Medicine; November 2012	
Expert Opinion	Expert Review of Neurotherapeutics	Cohen SP <i>et al.</i> Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment. <i>Expert Review of Neurotherapeutics</i> 2013;13(1):99-116	<p>Abstract: Sacroiliac joint (SIJ) pain is an underappreciated 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. Owing in part to its size and heterogeneity, the pain referral patterns of the SIJ are extremely variable. Although no single physical examination or historical feature can reliably identify a painful SIJ, studies suggest that a battery of three or more provocation tests can predict response to diagnostic blocks. Evidence supports both intra- and extra-articular causes for SIJ pain, with clinical studies demonstrating intermediate-term benefit for both intra- and extra-articular steroid injections. In those who fail to experience sustained relief from SIJ injections, radiofrequency denervation may provide significant relief lasting up to 1 year. This review covers all aspects of SIJ pain, with the treatment section being primarily focused on procedural interventions.</p> <p>Unable to get access to full text.</p>
Meta-analysis	Pain Physician	Manchikanti L <i>et al.</i> An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. <i>Pain Physician</i> 2013;16(2):1533-3159	<p>Abstract: OBJECTIVE: To develop evidence-based clinical practice guidelines for interventional techniques in the diagnosis and treatment of chronic spinal pain. METHODOLOGY: Systematic assessment of the literature. EVIDENCE: Lumbar Spine The evidence for accuracy of diagnostic selective nerve root blocks is limited; whereas for lumbar provocation discography, it is fair. The evidence for diagnostic lumbar facet joint nerve blocks and diagnostic sacroiliac intraarticular injections is good with 75% to 100% pain relief as criterion standard with controlled local anesthetic or placebo blocks. The evidence is good in managing disc herniation or radiculitis for caudal, interlaminar, and transforaminal epidural injections; fair for axial or discogenic pain without disc herniation, radiculitis or facet joint pain with caudal, and interlaminar epidural injections, and limited for transforaminal epidural injections; fair for spinal stenosis with caudal, interlaminar, and transforaminal epidural injections; and fair for post surgery syndrome with caudal epidural injections and limited with transforaminal epidural</p>

		<p>injections.</p> <p>The evidence for therapeutic facet joint interventions is good for conventional radiofrequency, limited for pulsed radiofrequency, fair to good for lumbar facet joint nerve blocks, and limited for intraarticular injections.</p> <p>For sacroiliac joint interventions, the evidence for cooled radiofrequency neurotomy is fair; limited for intraarticular injections and periarticular injections; and limited for both pulsed radiofrequency and conventional radiofrequency neurotomy.</p> <p>For lumbar percutaneous adhesiolysis, the evidence is fair in managing chronic low back and lower extremity pain secondary to post surgery syndrome and spinal stenosis.</p> <p>For intradiscal procedures, the evidence for intradiscal electrothermal therapy (IDET) and biaculooplasty is limited to fair and is limited for discTRODE.</p> <p>For percutaneous disc decompression, the evidence is limited for automated percutaneous lumbar discectomy (APLD), percutaneous lumbar laser disc decompression, and Dekompressor; and limited to fair for nucleoplasty for which the Centers for Medicare and Medicaid Services (CMS) has issued a noncoverage decision.</p> <p>II. Cervical Spine</p> <p>The evidence for cervical provocation discography is limited; whereas the evidence for diagnostic cervical facet joint nerve blocks is good with a criterion standard of 75% or greater relief with controlled diagnostic blocks.</p> <p>The evidence is good for cervical interlaminar epidural injections for cervical disc herniation or radiculitis; fair for axial or discogenic pain, spinal stenosis, and post cervical surgery syndrome.</p> <p>The evidence for therapeutic cervical facet joint interventions is fair for conventional cervical radiofrequency neurotomy and cervical medial branch blocks, and limited for cervical intraarticular injections.</p> <p>III. Thoracic Spine</p> <p>The evidence is limited for thoracic provocation discography and is good for diagnostic accuracy of thoracic facet joint nerve blocks with a criterion standard of at least 75% pain relief with controlled diagnostic blocks.</p> <p>The evidence is fair for thoracic epidural injections in managing thoracic pain.</p> <p>The evidence for therapeutic thoracic facet joint nerve blocks is fair, limited for radiofrequency neurotomy, and not available for thoracic intraarticular injections.</p> <p>IV. Implantables</p> <p>The evidence is fair for spinal cord stimulation (SCS) in managing patients with failed back surgery syndrome (FBSS) and limited for implantable intrathecal drug administration systems.</p> <p>ANTICOAGULATION</p> <p>There is good evidence for risk of thromboembolic phenomenon in patients with antithrombotic therapy if discontinued, spontaneous epidural hematomas with or without traumatic injury in patients with or without anticoagulant therapy to discontinue or normalize INR with warfarin therapy, and the lack of necessity of discontinuation of nonsteroidal anti-inflammatory drugs (NSAIDs), including low dose aspirin prior to performing interventional techniques.</p> <p>There is fair evidence with excessive bleeding, including epidural hematoma formation with interventional techniques when antithrombotic therapy is continued, the risk of higher thromboembolic phenomenon than epidural hematomas with discontinuation of antiplatelet therapy prior to interventional techniques and to continue phosphodiesterase inhibitors (dipyridamole, cilostazol, and Aggrenox).</p> <p>There is limited evidence to discontinue antiplatelet therapy with platelet aggregation inhibitors to avoid</p>
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			<p><u>Summary of evidence</u> <i>"The evidence is fair for cooled radiofrequency neurotomy; limited for short-term and long-term relief from intraarticular steroid injections; limited for periarticular injections with steroids or botulinum toxin; and limited for both pulsed radiofrequency."</i></p> <p><u>Complications</u> Complications from SIJ interventions are "exceedingly rare". "Most common complications of intraarticular injections and periarticular injections are 2-fold relating to the needle placement or administration of various drugs." <i>"Most side effects such as local swelling, pain at the site of the needle insertion, and pain in the extremities are shortlived and self-limited. More serious complications may include neural trauma, injection into the intervertebral foramina, hematoma formation, and sciatic nerve injury. Infectious complications including intraarticular abscess, systemic infection, and even meningitis... The side effects related to the administration of steroids and local anesthetics are similar to other interventions... In addition, minor complications such as lightheadedness, flushing, sweating, nausea, hypotension, syncope, have been reported."</i></p> <p><u>Recommendations</u> <i>"Based on the comprehensive review of the literature, there is good evidence that diagnostic blockade with controlled blocks provides better selection criteria than without diagnostic blocks. In addition, based on the comprehensive review of the literature for therapeutic purposes, the only effective modality with fair evidence appears to be cooled radiofrequency neurotomy after appropriate diagnosis confirmed by diagnostic sacroiliac joint injections. However, evidence is emerging for intraarticular injections, even though it is limited at the present time, which may be used in selected cases with or without periarticular injections."</i></p>
Systematic review	Pain Physician	Simopoulos TT <i>et al.</i> A systematic evaluation of prevalence and diagnostic accuracy of sacroiliac joint interventions. <i>Pain Physician</i> 2012;15(3):1533-3159	<p>Abstract:</p> <p>BACKGROUND: The contributions of the sacroiliac joint to low back and lower extremity pain have been a subject of considerable debate and research. It is generally accepted that 10% to 25% of patients with persistent mechanical low back pain below L5 have pain secondary to sacroiliac joint pathology. However, no single historical, physical exam, or radiological feature can definitively establish a diagnosis of sacroiliac joint pain. Based on present knowledge, a proper diagnosis can only be made using controlled diagnostic blocks. The diagnosis and treatment of sacroiliac joint pain continue to be characterized by wide variability and a paucity of the literature.</p> <p>OBJECTIVE: To evaluate the accuracy of diagnostic sacroiliac joint interventions.</p> <p>STUDY DESIGN: A systematic review of diagnostic sacroiliac joint interventions.</p> <p>METHODS: Methodological quality assessment of included studies was performed using Quality Appraisal of Reliability Studies (QAREL). Only diagnostic accuracy studies meeting at least 50% of the designated inclusion criteria were utilized for analysis. Studies scoring less than 50% are presented descriptively and analyzed critically. The level of evidence was classified as good, fair, or poor based on the quality of evidence developed by the United States Preventive Services Task Force (USPSTF). Data sources included relevant literature identified through searches of PubMed and EMBASE from 1966 to December 2011, and manual searches of the bibliographies of known primary and review articles.</p>

			<p>OUTCOME MEASURES: In this evaluation we utilized controlled local anesthetic blocks using at least 50% pain relief as the reference standard.</p> <p>RESULTS: The evidence is good for the diagnosis of sacroiliac joint pain utilizing controlled comparative local anesthetic blocks. The prevalence of sacroiliac joint pain is estimated to range between 10% and 62% based on the setting; however, the majority of analyzed studies suggest a point prevalence of around 25%, with a false-positive rate for uncontrolled blocks of approximately 20%. The evidence for provocative testing to diagnose sacroiliac joint pain was fair. The evidence for the diagnostic accuracy of imaging is limited.</p> <p>LIMITATIONS: The limitations of this systematic review include a paucity of literature, variations in technique, and variable criterion standards for the diagnosis of sacroiliac joint pain.</p> <p>CONCLUSIONS: Based on this systematic review, the evidence for the diagnostic accuracy of sacroiliac joint injections is good, the evidence for provocation maneuvers is fair, and evidence for imaging is limited.</p>
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