

Greater Manchester EUR Policy Statement on:

Out of contract spinal procedures

GM Ref: GM018

Version: 1.1 (March 2017)



Commissioning Statement

Out of contract spinal procedures	
Policy Exclusions	<p>This policy does not cover those areas routinely commissioned by CCGs or NHS England.</p> <p>Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).</p>
Policy Inclusion Criteria	<p>Funding Mechanism</p> <p>If the requested procedure is NOT commissioned clinicians can submit an individual funding request outside of this guidance if they feel there is a good case for clinical exceptionality. Requests on the grounds of exceptionality should be submitted with all relevant supporting evidence, which <u>must</u> be provided with the request.</p> <p>If the procedure IS commissioned for certain criteria, this will be stated below.</p> <p>Endoscopic laser foraminoplasty</p> <p>Endoscopic laser foraminoplasty is NOT commissioned and should only be undertaken within agreed and funded clinical trials.</p> <p>Lower back surgery for chronic pain</p> <p>Lower back surgery for chronic pain <u>alone</u> is NOT commissioned.</p> <p>If there is an underlying condition causing the pain then that is commissioned within local contracts according to local pathways of care.</p> <p>Percutaneous endoscopic laser discectomy and percutaneous intradiscal laser ablation</p> <p>Percutaneous endoscopic laser discectomy and percutaneous intradiscal laser ablation are not routinely commissioned except in cases where commissioned treatments have failed or are contraindicated.</p> <p>Funding Mechanism</p> <p>Individual prior approval provided the patient meets the above criteria. Requests should be submitted with all relevant supporting evidence, which <u>must</u> be provided with the request.</p> <p>Any other new or experimental procedure on the spine</p> <p>Funding Mechanism</p> <p>Individual funding request (exceptional case) approval: Applications should be made using the process outlined in the GM Experimental & Unproven Treatments Policy. Requests should be submitted with all relevant supporting evidence, which <u>must</u> be provided with the request.</p>
Clinical Exceptionality	<p>Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality.</p> <p>Exceptionality means 'a person to which the general rule is not applicable'. Greater</p>

Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:

- Significantly different to the general population of patients with the condition in question.

and as a result of that difference

- They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

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Policy Statement

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

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

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

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

Equality & Equity Statement

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

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

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

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

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

Aims and Objectives

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

- reducing the variation in access to treatments/procedures.

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

Rationale behind the policy statement

Back pain is a difficult to manage symptom with a great many treatment options available - this policy seeks to ensure that all patient are managed using effective interventions and best practice. Emerging treatments should be offered with an emphasis on patient safety and expanding the knowledge base. New and unproven therapies should be delivered within a trial protocol to ensure patient safety and for all therapies offered the benefit should outweigh the risk of the intervention.

Spinal surgery is mostly covered by current commissioning arrangements, however there are a few procedures where the evidence of effectiveness suggests low clinical value or where there is insufficient evidence to assess their effectiveness.

Areas routinely commissioned by the CCGs are:

For acute disease / injury:

- A spinal triage service.
- Initial assessments
- Patients admitted with a spinal condition having no procedure.
- Patients having non-specialised spinal surgery at spinal 'spoke' or 'hub' hospitals (together with the necessary associated support services).

For degenerative disease of the spine:

- Anterior cervical discectomy +/- fusion (incl. revision surgery)
- Posterior cervical decompressions (incl. revision surgery)
- Posterior instrumented fusion / stabilisation and/or (1 or 2 level) posterior lumbar decompression / discectomy (incl. revision surgery)
- Biopsy or radiofrequency or vertebral cement augmentation procedures (whole spine)

NHS England routinely commissions complex spinal surgery, most disc replacement surgery, most cancer related surgery (except palliative) and surgery for spinal deformity including:

- Any cervical spine procedure involving implants except those for anterior cervical discectomy and fusion
- All thoracic spinal surgery
- All anterior lumbar spine surgery
- Posterior instrumented spinal fusion / stabilisation more than 2 levels
- All surgery for spinal deformity
- All surgical procedures for spinal infection / palliative metastatic tumours and trauma (excluding biopsy)
- All spinal surgery for potentially curative spinal tumours including biopsy

The procedures covered by this policy are:

- Endoscopic laser surgery on the back including but not limited to foraminoplasty

- Percutaneous intradiscal ablation in the lumbar spine
- Cryoneurolysis
- Discectomy for lumbar prolapse
- Lower back surgery for chronic pain

NOTE: Facet joint injections and radiofrequency denervation are covered by separate policies.

Treatment / Procedure

Symptomatic herniation (prolapse) of a lumbar intravertebral disc is a common cause of chronic low back pain and sciatica. Disc herniation is a result of the protrusion of the nucleus pulposus through a tear in the annulus fibrosus. The annulus fibrosus may rupture completely, resulting in an extruded disc, or it may remain intact but stretched, resulting in a contained (bulging) disc prolapse. Protruding discs may compress one or more nerve roots, resulting in pain and numbness in the leg.

Current surgical treatment options include microdiscectomy, percutaneous intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation and percutaneous disc decompression using coblation. Surgical decompression is considered when there is nerve compression causing weakness or persistent symptoms that are unresponsive to conservative treatment.

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Figure 1: Normal spinal intradiscal space

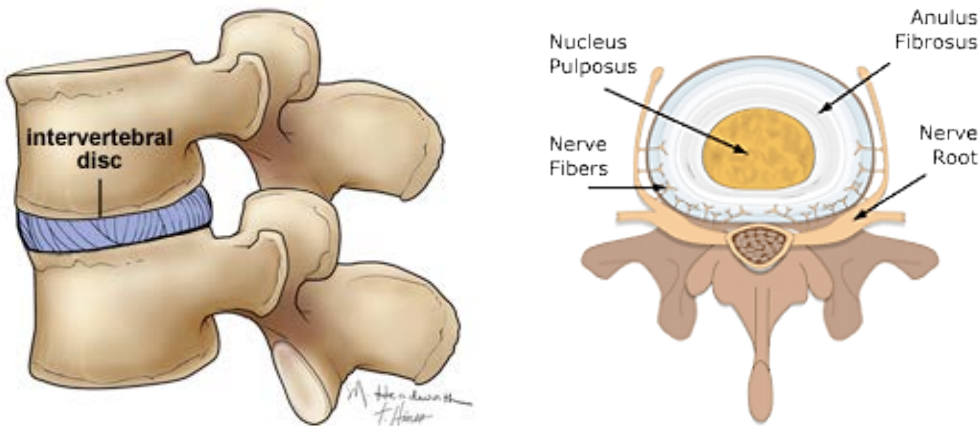
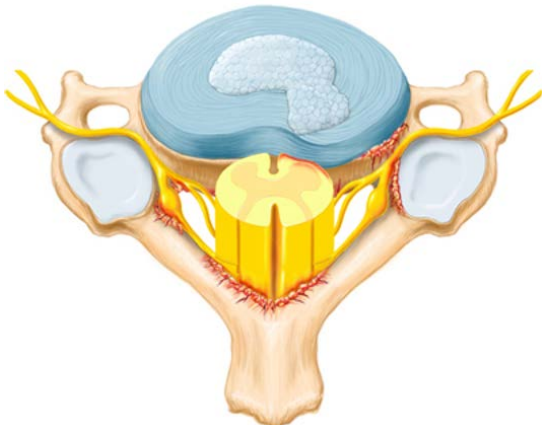


Figure 2: Herniated disc space showing pressure on the nerve root



Endoscopic Laser Foraminoplasty

Endoscopic laser foraminoplasty is used mainly to treat chronic back and leg pain from a variety of causes. Annually, 2-5% of people suffer acute back pain, and 0.5% of these have pain and neurological conditions requiring surgery. This endoscope-assisted laser technique is used to widen the lumbar exit foramina for nerves from the lumbar spine. A laser is inserted to ablate portions of the intervertebral disc that have protruded and caused narrowing of the foramina.

Cryoneurolysis

The destruction of a nerve by applying a very cold probe to it, e.g. one whose temperature is -321°F (the temperature of liquid nitrogen).

Percutaneous intradiscal ablation in the lumbar spine

The aim of percutaneous intradiscal laser ablation (also commonly referred to in the literature as percutaneous laser disc decompression) is to vaporise part of a prolapsed disc. It can only be carried out if the prolapse is contained (that is, the disc is bulging but the nucleus pulposus has not extruded through the annulus fibrosus).

The procedure is usually carried out under local anaesthesia and sedation, with the patient in the prone position. Under fluoroscopic guidance, a spinal needle is inserted through the annulus fibrosus into the nucleus pulposus, and an optical fibre is introduced through the needle. Laser energy is then delivered through the optical fibre to vaporise part of the nucleus pulposus.

Several types of laser are available for this procedure.

Current evidence on the safety and efficacy of percutaneous intradiscal laser ablation in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

Percutaneous endoscopic laser discectomy

Through a small incision in the back, the appropriate side and level of the lumbar spine is exposed using a small retractor port. The spinal canal is opened and, under endoscopic visualisation, the nerve root is decompressed by disc removal and laser vaporisation.

Epidemiology and Need

NICE estimates that between 2% to 5% of the population will suffer back pain with 0.5% of those going on to surgical intervention.

Area	Population (2011)	2%	0.5% of 2%	5%	0.5% of 5%
		Cases of back pain - lower estimate	Cases requiring surgery - lower estimate	Cases of back pain - upper estimate	Cases requiring surgery - upper estimate
Bolton	276,800	5,536	27.68	13,840	69.2
Bury	185,100	3,702	18.51	9,255	46.275
HMR	211,700	4,234	21.17	10,585	52.925
Manchester	503,100	10,062	50.31	25,155	125.775
Oldham	224,900	4,498	22.49	11,245	56.225
Salford	233,900	4,678	23.39	11,695	58.475

Stockport	283,300	5,666	28.33	14,165	70.825
T&G	219,300	4,386	21.93	10,965	54.825
Trafford	226,600	4,532	22.66	11,330	56.65
Wigan	317,800	6,356	31.78	15,890	79.45
Total GM	2,682,500	53,650	268.25	134,125	670.625

Adherence to NICE Guidance

This policy adheres fully to the recommendations made in NICE CG88; NICE IPG31; NICE IPG300 and NICE IPG357.

Audit Requirements

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

Date of Review

One year from the date of approval by Greater Manchester Association Governing Group and thereafter at a date agreed by the Greater Manchester EUR Steering Group, unless new evidence or technology is available sooner.

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

Glossary

Term	Meaning
Anterior	Situated toward the front of the body, also termed ventral in human anatomy because of the upright posture of humans.
Cervical	Relating to the neck.
Coblation	An advanced technology that uses gentle radiofrequency energy with a saline solution to remove tissue.
Cryoneurolysis	A procedure that involves "freezing" damaged nerves to relieve pain.
Discectomy	Surgical removal of the whole or a part of an intervertebral disc.
Endoscopic	A surgical procedure carried out through a specially designed tube (or endoscope)
Herniation/prolapse	A medical condition affecting the spine in which a tear in the outer, fibrous ring (anulus fibrosus) of an intervertebral disc (discus intervertebralis) allows the soft, central portion (nucleus pulposus) to bulge out.
Lumbar	Relating to the lower part of the back.
Microdiscectomy / microdecompression	A small portion of the bone over the nerve root and some of the disc material from under the nerve root is removed to relieve pressure on the nerve and provide room for the nerve to heal.

Posterior	Relating to the back of the body.
Thoracic	Relating to the thorax (chest).

References

1. Greater Manchester Effective Use of Resources Operational Policy
2. Commissioning Spinal Services: Getting the service back on track: A guide for commissioners of spinal services (January 2013), The National Spinal Taskforce

Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	20/07/2016
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	14/02/2017
Greater Manchester Association Governing Group	07/03/2017
Bury Clinical Commissioning Group	05/04/2017
Bolton Clinical Commissioning Group	24/03/2017
Heywood, Middleton & Rochdale Clinical Commissioning Group	07/03/2017
Central Manchester Clinical Commissioning Group	15/03/2017
North Manchester Clinical Commissioning Group	15/03/2017
Oldham Clinical Commissioning Group	07/03/2017
Salford Clinical Commissioning Group	07/03/2017
South Manchester Clinical Commissioning Group	15/03/2017
Stockport Clinical Commissioning Group	07/03/2017
Tameside & Glossop Clinical Commissioning Group	07/03/2017
Trafford Clinical Commissioning Group	21/03/2017
Wigan Borough Clinical Commissioning Group	03/05/2017

Appendix 1 – Evidence Review

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Search Strategy

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

Database	Result
NICE	<ul style="list-style-type: none"> • NICE CG88: Low back pain in adults: early management - – not cited here – available on request: <ul style="list-style-type: none"> ○ Do not refer people for intradiscal electrothermal therapy (IDET) – not cited here – available on request ○ Do not offer laser therapy, as a non-pharmacological therapy for low back pain. • NICE IPG300: Percutaneous endoscopic laser lumbar discectomy • NICE IPG357: Percutaneous intradiscal laser ablation in the lumbar spine • NICE IPG31: Endoscopic laser foraminoplasty • NICE Database for uncertainties in treatments: Posterior discectomy for lumbar disc herniations Safety and efficacy of classic, microsurgical, and endoscopic lumbar discectomies using a posterior approach. – No citation but evidence can be reviewed via NHS evidence (DUETS website not maintained after Jan 2016)
NHS Evidence and NICE CKS	Cochrane paper (see below)
Cochrane	Surgical interventions for lumbar disc prolapse: (Cochrane Review) , Gibson JNA, Waddell G, 18 th April 2007
York	Percutaneous endoscopic laser discectomy , Boulton M, Fraser R D, Jones N, Osti O, Dohrmann P, Donnelly P, Liddell J, Maddern G J, Aust N Z J Surg. 2000 Jul;70(7):475-9.
BMJ Clinical Evidence	BMJ Clinical Evidence Review: Low back pain (chronic) Roger Chou Search date: April 2009
General Search (Google)	<ul style="list-style-type: none"> • Multiple sites relating to chronic pain • NHS choices general information on discectomy (not cited here)
Other	<ul style="list-style-type: none"> • RCS Commissioning Guide – Low Back Pain: Broad Principles of the patient pathway (does not cover these procedures so not cited here) • Percutaneous Treatment of Intervertebral Disc Herniation, Buy X, Gangi A, Semin Intervent Radiol. 2010 Jun; 27(2): 148–159.

Summary of the evidence

The evidence for percutaneous endoscopic laser discectomy is limited, but is supportive of its use in certain circumstances and as part of a trial or audit. At present this procedure is considered experimental and unproven.

The evidence for percutaneous intradiscal laser ablation in the lumbar spine Percutaneous is limited but is supportive of its use in certain circumstances and as part of a trial or audit. At present this procedure is considered experimental and unproven.

There is little evidence of effectiveness for cryoneurolysis in place of thermocoagulation.

The evidence suggests that endoscopic laser foraminoplasty is an unproven technique and should only be undertaken within the safeguards of a clinical trial.

The evidence suggests that lower back surgery should not be undertaken for chronic pain alone but should be done if indicated to address any underlying condition causing the pain.

The evidence

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

1. LEVEL 1: SYSTEMATIC REVIEW

Percutaneous endoscopic laser discectomy, Boulton M, Fraser R D, Jones N, Osti O, Dohrmann P, Donnelly P, Liddell J, Maddern G J, Aust N Z J Surg. 2000 Jul;70(7):475-9.

Results of the review

Data from five studies were reported in the review (395 patients), including three reports of time series and two case series.

Study quality: No controlled, blinded or randomised trials were identified. The quality of information available was low and the highest level of evidence came from time series studies.

Time series (3 reports):

1. One report appeared to represent follow-up at 2 years of a selected sub-group of 100 patients out of 223 patients whose results at one year were reported. Assessment was undertaken by phone and there was potential for interviewer bias.

At one year: results were rated as excellent (McNab criteria) in 187/222 (84.2%). 4.5% required open laminectomy. 5.4% required second PELD at same level. 5.8% were rated as fair to poor (failure). Complication rate = 1.8%. Resumption of normal activities at mean of 32.4 days (standard deviation = 42.5 days). Complications included: infection (1); suspected discitis (1); contralateral transient dermatomal discomfort (1); and transient nerve block (1). At two years, results were reported for a selected sub-group. No details were given of the method of selection and results excluded the four patients who experienced complications.

2. **The other time series (26 patients):** after one year, three patients required open operation (11%), recovery rate was 64.6% (+/- 27.3) but the three patients requiring open operation were omitted from

this score. This study lacked statistical power and used a different outcome (Japanese Orthopaedic Association scoring system) from the other study.

Case series (2 studies, 46 patients): These were both conducted by the same author. One included only six patients with apparent subjective assessment of symptoms following surgery. In the larger series (40 patients), ratings of outcome were not defined.

Authors' conclusions: Given the extremely low level of evidence available for this procedure it was recommended that the procedure be regarded as experimental until results are available from a controlled clinical trial, ideally with random allocation to an intervention and control group.

CRD commentary: The aims were stated and inclusion criteria defined in terms of patients, intervention, outcomes, and study design. The search included several relevant potential sources and methods used to select studies were described. Limiting included studies to those in the English language may have omitted some higher quality studies and no attempt was made to locate unpublished studies thus raising the possibility of publication bias. Some aspects of validity were discussed though no formal assessment, other than classification of the level of evidence by study design, was undertaken. Methods used to assess validity and extract data were not described. Relevant information on the included studies was presented in tabular format. Given the differences between studies, a narrative review was appropriate. The evidence supports the authors' conclusions.

Implications of the review for practice and research

Practice: The authors state that the safety and/or efficacy of the procedure cannot be determined at the present time, owing to an incomplete and/or poor-quality evidence base.

Research: The authors recommend that a controlled clinical trial (ideally with random allocation to an intervention and control group) be conducted to establish the safety and/or efficacy of this procedure. They further recommend that RCTs be carried out testing PELD against a placebo, chemonucleolysis or open discectomy.

2. LEVEL 1: SYSTEMATIC REVIEW

Surgical interventions for lumbar disc prolapse: (Cochrane Review), Gibson JNA, Waddell G, 18 April 2007

Plain language summary

The effects of surgical treatments for individuals with 'slipped' lumbar discs

Prolapsed lumbar discs ('slipped disc', 'herniated disc') account for less than five percent of all low-back problems, but are the most common cause of nerve root pain ('sciatica'). Ninety percent of acute attacks of sciatica settle with non-surgical management. Surgical options are usually considered for more rapid relief in the minority of patients whose recovery is unacceptably slow.

This updated review considers the relative merits of different forms of surgical treatments by collating the evidence from 40 randomized trials and two quasi-randomized controlled trials (5197 participants) on:

- (i) Discectomy - surgical removal of part of the disc
- (ii) Microdiscectomy - use of magnification to view the disc and nerves during surgery
- (iii) Chemonucleolysis - injection of an enzyme into a bulging spinal disc in an effort to reduce the size of the disc

Despite the critical importance of knowing whether surgery is beneficial, only three trials directly compared discectomy with nonsurgical approaches. These provide suggestive rather than conclusive results. Overall, surgical discectomy for carefully selected patients with sciatica due to a prolapsed lumbar disc appears to provide faster relief from the acute attack than non-surgical management.

However, any positive or negative effects on the lifetime natural history of the underlying disc disease are unclear. Microdiscectomy gives broadly comparable results to standard discectomy. There is insufficient evidence on other surgical techniques to draw firm conclusions.

Trials showed that discectomy produced better outcomes than chemonucleolysis, which in turn was better than placebo. For various reasons including concerns about safety, chemonucleolysis is not commonly used today to treat prolapsed disc.

Many trials provided limited information on complications, but generally included recurrence of symptoms, need for additional surgery and allergic reactions (chemonucleolysis).

Many of the trials had major design weaknesses that introduced considerable potential for bias. Therefore, the conclusions of this review should be read with caution.

Future trials should be designed to reduce potential bias. Future research should explore the optimal timing of surgery, patient-centred outcomes, costs and cost-effectiveness of treatment options, and longer-term results over a lifetime perspective.

3. LEVEL 1: SYSTEMATIC REVIEW

BMJ Clinical Evidence Review: Low back pain (chronic), Roger Chou, Search date: April 2009

Radiofrequency denervation

Symptom improvement: Compared with sham treatment or placebo We don't know whether radiofrequency denervation is more effective than placebo at reducing pain in people with presumed facet joint or discogenic low back pain (very low-quality evidence).

Functional improvement: Compared with sham treatment or placebo We don't know whether radiofrequency denervation is more effective at improving function in people with presumed facet joint or discogenic low back pain (very low-quality evidence).

Benefits

Radiofrequency denervation versus no treatment/sham treatment or usual care: We found one systematic review (search date 2008; 8 RCTs), which evaluated radiofrequency denervation for non-radicular low back pain. Six RCTs included in the review (322 people) evaluated radiofrequency denervation for presumed facet joint pain versus sham treatment, and one RCT (49 people) included in the review evaluated radiofrequency denervation for presumed discogenic back pain versus lidocaine injection. Four RCTs of radiofrequency denervation for presumed facet joint pain were rated higher quality by the review. The first higher-quality RCT included in the review (40 people selected by controlled facet joint blocks and an ablation technique believed to be optimal) found that radiofrequency denervation improved generalised, back, and leg pain compared with sham treatment at 6 months (0–10 visual analogue scale [VAS]: –1.4 points to –1.6 points), but the difference was not statistically significant for back pain (the main symptom thought to be associated with facet pain). The review reported that baseline scores in the radiofrequency denervation group were on average 1.6 points higher, which suggests inadequate randomisation. The review reported that the other three higher-quality RCTs used uncontrolled diagnostic facet joint blocks to select the people included in the trials, and, may have used suboptimal ablation techniques, and all reported conflicting results. The second higher-quality RCT (30 people) found that radiofrequency denervation moderately improved mean VAS pain and Oswestry Disability Index (ODI) scores through 2 months (pain: mean VAS score on a 0–10 VAS: –2.4 with radiofrequency v –0.4 with placebo; $P < 0.05$; ODI: –11.1 with radiofrequency denervation v +1.7 with placebo; $P < 0.05$). The third higher-quality RCT (70 people) found radiofrequency denervation superior to sham treatment for mean improvement in Roland Morris Disability Questionnaire (RMDQ) scores at 4 weeks (RMDQ scores: –8.4 with radiofrequency denervation v –2.2 with placebo; $P = 0.05$), but there were no statistically significant differences in ODI or VAS pain scores between groups (reported as not significant; P value not reported). However, the RCT found no significant difference between groups for RMDQ score at 12 weeks. The fourth higher-quality RCT (82 people) found no differences between radiofrequency denervation compared with sham treatment on any outcome (further data not reported). The first lower-quality RCT included in the review (60 people) found that conventional but not pulsed radiofrequency denervation improved pain (VAS 0–10 scale: 0.8–1.5 points, significance not reported) and function (4–6 points on the ODI; significance not reported) compared with sham treatment at 1 year. The review reported that the second lower-quality RCT had serious methodological shortcomings, including lack of intention-to-treat analysis, and therefore was not reported. The one RCT included in the review (49 people) that evaluated radiofrequency for presumed discogenic pain (based on positive

lumbar provocative discography) found that radiofrequency denervation of the ramus communicans nerves significantly improved pain, SF-36 bodily pain, and SF-36 physical function scores compared with lidocaine injection after 4 months (pain: mean VAS [0–10 scale] pain scores: 3.8 with radiofrequency denervation v 6.3 with lidocaine injection; P <0.05; SF-36 bodily pain: 44 with radiofrequency denervation v 32 with lidocaine injection; P <0.05; SF-36 physical function: 59 with radiofrequency denervation v 46 with lidocaine injection; P <0.05). The review reported that the RCT was of lower quality.

Harms

Radiofrequency denervation versus no treatment/sham treatment or usual care: The review reported that one of the included RCTs found a case of mild, subjective, and transient lower limb weakness after radiofrequency denervation. The review included two other RCTs that found no difference in adverse effects between radiofrequency denervation compared with sham treatment, although radiofrequency denervation was associated with trends towards increased post-procedural pain.

Comment

The RCTs in the review included people with pain presumably arising from the facet joint or intervertebral disc. However, the accuracy of methods for identifying patients with facet joint or discogenic pain is unknown. RCTs of radiofrequency denervation for presumed facet joint pain are difficult to interpret because higher-quality studies reported conflicting studies, some RCTs may have used suboptimal techniques, and the only RCT to use controlled facet joint diagnostic blocks to select patients for inclusions reported baseline differences between the treatment and sham groups.

4. LEVEL N/A: NICE IPG

NICE IPG300: Percutaneous endoscopic laser discectomy

1. Guidance

- 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to undertake percutaneous endoscopic laser lumbar discectomy should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information.
 - Audit and review clinical outcomes of all patients having percutaneous endoscopic laser lumbar discectomy (see section 3.1).
- 1.3 Surgeons undertaking this procedure should have specific training in the use of lasers and in endoscopy of the spinal canal.
- 1.4 NICE encourages further research into percutaneous endoscopic laser lumbar discectomy and may review the procedure on publication of further evidence. Research studies should provide long-term outcome data.

2. The procedure

2.1 *Indications and current treatments*

- 2.1.1 Symptomatic lumbar disc prolapse occurs when part of the intervertebral disc protrudes into the spinal canal and compresses one or more nerve roots.
- 2.1.2 Conservative treatments include analgesics, non-steroidal anti-inflammatory medication and physical therapy. Epidural steroid injections can also be used. Surgery to remove disc material is considered if there is evidence of severe nerve compression or persistent symptoms that are unresponsive to conservative treatment. Surgical techniques include open discectomy or minimally invasive alternatives using percutaneous approaches.

2.2 *Outline of the procedure*

2.2.1 The procedure may be carried out with the patient under local anaesthesia to enable patient feedback on symptomatic relief. Through a small incision in the back, the appropriate side and level of the lumbar spine is exposed using a small retractor port. The spinal canal is opened and, under endoscopic visualisation, the nerve root is decompressed by disc removal and laser vaporisation.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure.

2.3 Efficacy

2.3.1 A case series of 300 patients treated with percutaneous endoscopic laser lumbar discectomy reported that 67% (186/279) of patients with central disc prolapse, 67% (8/12) of patients with lateral prolapse and 0 of 9 patients with stenosis and herniated nucleus pulposus were able to return to work and had increased mobility at 6-month follow-up. In a case series of 67 patients with prolapsed lumbar discs refractory to conservative treatment, the mean period before return to work was 7 weeks (range 1 to 48 weeks) following percutaneous laser lumbar discectomy.

2.3.2 The case series of 300 patients reported a reduced need for pain medication (from narcotic to other analgesic agents) in 32% (90/279) of patients with a central disc prolapse, 25% (3/12) of patients with a lateral prolapse, and 8 of 9 patients with stenosis and herniated nucleus pulposus at 6-month follow-up. A case series of 67 patients reported that the mean Oswestry Disability Index score (a scale from 0 to 100; lower scores indicate less pain and better functional capacity) improved significantly from 57.43 points at baseline to 11.52 points at a minimum follow-up of 18 months ($p < 0.01$ as stated in the literature).

2.3.3 A case series of 43 patients with recurrent disc prolapse after previous open discectomy reported that following percutaneous endoscopic laser lumbar discectomy, 28% (12/43) of patients had an 'excellent' outcome based on the MacNab criteria (a four-grade classification based on pain and functional capacity; not otherwise defined) at a mean follow-up of 31 months.

2.3.4 The Specialist Advisers considered key efficacy outcomes to include pain relief, pain recurrence and return to work.

2.4 Safety

2.4.1 Three case series of 67, 300 and 43 patients reported need for a subsequent operation in 4% (3/67), 2% (5/300) and 2% (1/43) of patients, respectively (minimum 18-month follow-up, median follow-up 6 months, mean follow-up 31 months, respectively).

2.4.2 The case series of 300 patients reported sympathetic mediated pain within 7 days of discharge in 5% (15/300) of patients. The case series of 67 patients reported thecal sac injury with cerebrospinal fluid leakage in 3% (2/67) of patients, but open repair was not needed.

2.4.3 The case series of 43 and 67 patients reported transient dysaesthesia following the procedure in 5% (2/43) and 13% (9/67) of patients, respectively. In the case series of 67 patients, dysaesthesia had resolved in all patients within 1 month of the procedure.

2.4.4 The Specialist Advisers considered theoretical adverse events to include a higher risk of nerve or dural injury because of the poor field of vision and disorientation, and a higher probability of missed fragments. One Specialist Adviser stated that there had been cases of heat damage to the cauda equine when laser was used for lumbar discectomy with concomitant foraminoplasty.

2.5 Other comments

2.5.1 The Committee noted that the extent to which laser ablation was used, instead of or in addition to mechanical methods of removing prolapsed disc material, was unclear in much of the published evidence.

3. Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed audit support (which is for use at local discretion).

3.2 NICE has published interventional procedures guidance on automated percutaneous mechanical lumbar discectomy, endoscopic laser foraminoplasty and laser lumbar discectomy.

5. LEVEL N/A: NICE IPG

NICE IPG357: Percutaneous intradiscal laser ablation in the lumbar spine (replaces IPG27)

1. Guidance

- 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal laser ablation in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression.

2. The procedure

2.1 Indications and current treatments

- 2.1.1 Symptomatic herniation (prolapse) of a lumbar intravertebral disc is a common cause of chronic low back pain and sciatica. Disc herniation is a result of the protrusion of the nucleus pulposus through a tear in the annulus fibrosus. The annulus fibrosus may rupture completely, resulting in an extruded disc, or it may remain intact but stretched, resulting in a contained (bulging) disc prolapse. Protruding discs may compress one or more nerve roots, resulting in pain and numbness in the leg.
- 2.1.2 Conservative treatment options include rest, analgesic or anti-inflammatory medication, epidural injection and physical therapies. Current surgical treatment options include microdiscectomy, percutaneous intradiscal electrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation and percutaneous disc decompression using coblation. Surgical decompression is considered when there is nerve compression causing weakness or persistent symptoms that are unresponsive to conservative treatment.

2.2 Outline of the procedure

- 2.2.1 The aim of percutaneous intradiscal laser ablation (also commonly referred to in the literature as percutaneous laser disc decompression) is to vaporise part of a prolapsed disc. It can only be carried out if the prolapse is contained (that is, the disc is bulging but the nucleus pulposus has not extruded through the annulus fibrosus).
- 2.2.2 The procedure is usually carried out under local anaesthesia and sedation, with the patient in the prone position. Under fluoroscopic guidance, a spinal needle is inserted through the annulus fibrosus into the nucleus pulposus, and an optical fibre is introduced through the needle. Laser energy is then delivered through the optical fibre to vaporise part of the nucleus pulposus.
- 2.2.3 Several types of laser are available for this procedure.

2.3 Efficacy

- 2.3.1 A non-randomised comparative study of 1000 patients reported 'excellent' or 'good' MacNab criteria scores (pain relieved by 50% or more and improved motor function) in 84% (419/500) of patients treated by the procedure and 86% (428/500) of patients treated by microdiscectomy at mean 2-year follow-up (significance not stated).
- 2.3.2 A non-randomised comparative study of 106 patients reported 'excellent' MacNab criteria scores (pain relieved by 75% or more and no limitation of motor function) in 48% (29/60) of patients treated by the procedure compared with 48% (22/46) of patients treated by automated percutaneous lumbar discectomy (APLD) (follow-up not stated; difference reported as not significant).
- 2.3.3 A case series of 518 patients reported an overall success rate (using MacNab criteria; not otherwise described) of 75% (absolute figures and follow-up not stated).
- 2.3.4 The non-randomised comparative study of 1000 patients reported reoperation for herniation or persistent leg or back pain in 3% (16/500) of patients treated by the procedure and 7% (35/500) of patients treated by microdiscectomy at a mean 2-year follow-up.
- 2.3.5 A case series of 576 patients reported that 61% of patients were satisfied with the overall outcome of the procedure (absolute figures and follow-up not stated).

2.3.6 The Specialist Advisers listed key efficacy outcomes as recurrence rate, reoperation rate, leg and back pain score, Oswestry Disability Index score and successful decompression.

2.4 Safety

2.4.1 Aseptic discitis (post-procedural inflammatory pain) requiring up to 3 days of hospitalisation with steroid treatment was reported in 2 patients treated by the procedure in a non-randomised comparative study of 81 patients. Case series of 576 and 518 patients reported aseptic discitis in 4 and 2 patients respectively. In the second series both patients developed aseptic discitis up to 4 days after the procedure (not otherwise described) and were treated successfully with bed rest and analgesics.

2.4.2 Septic discitis 3 days after the procedure (confirmed by magnetic resonance imaging [MRI] and needle puncture culture, which was positive for *Staphylococcus aureus*) was reported in 2 patients in the case series of 518 patients. Both patients were treated with parenteral vancomycin for 6 weeks. Intervertebral disc infection (not otherwise described) was reported in no patients treated by the procedure and 1 patient treated by APLD in the nonrandomised comparative study of 106 patients (timing of event not stated).

2.4.3 Subchondral vertebral osteonecrosis (confirmed by MRI) was reported in 2% (4/ 182) of patients in the case series of 182 patients: 1 patient underwent surgical treatment for persistent severe back pain, which resolved 1 year after the initial procedure, and 3 patients had conservative management of their pain which had diminished at 2-year follow-up after the initial procedure.

2.4.4 A case series of 10 patients who required salvage operations after the procedure to address herniated discs reported that all patients showed evidence of heat-induced cell necrosis and carbonisation, with herniating masses completely compressing and adhering to nerve roots.

2.4.5 The Specialist Advisers stated that bowel perforation was described in the literature. They considered theoretical adverse events to include dural tear, heat damage due to incorrect placement of the probe, recurrent protrusion of disc, nerve damage, infection, vertebral body collapse, loss of disc height and perineural scarring.

6. LEVEL N/A: NICE IPG

NICE IPG31: Endoscopic laser foraminoplasty

1. Guidance

1.1 Current evidence of the safety and efficacy of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake endoscopic laser foraminoplasty should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Clinicians should ensure that appropriate arrangements are in place for audit or research. Further research into safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

2. The procedure

2.1 Indications

2.1.1 Endoscopic laser foraminoplasty is used mainly to treat chronic back and leg pain from a variety of causes. Annually, 2–5% of people suffer acute back pain, and 0.5% of these have pain and neurological conditions requiring surgery.

2.2 Outline of the procedure

2.2.1 This endoscope-assisted laser technique is used to widen the lumbar exit foramina for nerves from the lumbar spine. A laser is inserted to ablate portions of the intervertebral disc that have protruded and caused narrowing of the foramina.

2.3 Efficacy

2.3.1 The research on efficacy undertaken to date is based on case series only and has all been led by a single clinician. In general, pain was decreased after the procedure. For more details, refer to the sources of evidence section.

2.3.2 The Specialist Advisors believed the efficacy of this procedure to be unproven.

2.4 Safety

2.4.1 The research on safety undertaken to date has all been led by a single clinician. The rates of reported complications were low, with discitis and neurological deficit being the most common (both with incidence lower than 1%). For more details, refer to the sources of evidence section.

2.4.2 The Specialist Advisors noted a number of potential complications including nerve injury and infection.

7. LEVEL 1: SYSTEMATIC REVIEW

NICE CG88: Early management of persistent non-specific low back pain

Persistent low back pain (i.e. a single episode of non-specific low back pain lasting 12 months or more)

NICE CG88 SUGGESTS THE FOLLOWING KEY PRIORITIES FOR IMPLEMENTATION:

Information, education and patient preferences

- Provide people with advice and information to promote self-management of their low back pain.
- Offer one of the following treatment options, taking into account patient preference: an exercise programme (see section 1.3.3), a course of manual therapy (see section 1.4.1) or a course of acupuncture (see section 1.6.1). Consider offering another of these options if the chosen treatment does not result in satisfactory improvement.

Physical activity and exercise

- Consider offering a structured exercise programme tailored to the person:
 - This should comprise up to a maximum of eight sessions over a period of up to 12 weeks.
 - Offer a group supervised exercise programme, in a group of up to 10 people.
 - A one-to-one supervised exercise programme may be offered if a group programme is not suitable for a particular person.

Manual therapy

- Consider offering a course of manual therapy, including spinal manipulation, comprising up to a maximum of nine sessions over a period of up to 12 weeks.

Invasive procedures

- Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks.
- Do not offer injections of therapeutic substances into the back for non-specific low back pain.

Combined physical and psychological treatment programme

- Consider referral for a combined physical and psychological treatment programme, comprising around 100 hours over a maximum of 8 weeks, for people who:
 - have received at least one less intensive treatment (see section 1.2.5) **and**
 - have high disability and/or significant psychological distress.

Assessment and imaging

- Do not offer X-ray of the lumbar spine for the management of non-specific low back pain.
- Only offer an MRI scan for non-specific low back pain within the context of a referral for an opinion on spinal fusion (see section 1.9).

Referral for surgery

- Consider referral for an opinion on spinal fusion for people who:
 - have completed an optimal package of care, including a combined physical and psychological treatment programme (see section 1.7) and

- still have severe non-specific low back pain for which they would consider surgery.

The manual therapies reviewed were spinal manipulation, spinal mobilisation and massage (see section 1.4 for further details). Collectively these are all manual therapy. Mobilisation and massage are performed by a wide variety of practitioners. Manipulation can be performed by chiropractors and osteopaths, as well as by doctors and physiotherapists who have undergone specialist postgraduate training in manipulation.

Summary of treatments that are not recommended by NICE CG88 for chronic low back pain

The National Institute for Health and Care Excellence (NICE) recommends that people with *non-specific* chronic low back pain that persists *for less than a year* should not be treated with, or referred for:

- Alexander technique: Although lessons in the Alexander technique are likely to be effective, this is not recommended for provision by the NHS, because exercise is likely to be more cost-effective. However, people may wish to arrange lessons in the Alexander technique for themselves.
- Massage: Although massage may be effective, this is not recommended for provision by the NHS, because other physical interventions are likely to be more cost-effective. However, people may wish to arrange massage for themselves.
- Percutaneous electrical nerve stimulation (PENS)
- Transcutaneous electrical nerve stimulation (TENS)
- Selective serotonin reuptake inhibitors (SSRIs)
- Injections of therapeutic substances into the back
- Laser therapy
- Interferential therapy
- Therapeutic ultrasound
- Lumbar supports
- Traction
- Radiofrequency facet joint denervation
- Intradiscal electrothermal therapy (IDET)
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- Neuroreflexive therapy

8. LEVEL 1: SYSTEMATIC REVIEW

BMJ Clinical Evidence Review: Low back pain (chronic), Roger Chou, Search date: April 2009

ABSTRACT

Introduction: Over 70% of people in developed countries develop low back pain (LBP) at some time. But recovery is not always favourable: 82% of non-recent-onset patients still experience pain 1 year later. Many patients with chronic LBP who were initially told that their natural history was good spend months or years seeking relief.

Methods and Outcomes: We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of oral drug treatments? What are the effects of injection therapy? What are the effects of non-drug treatments? What are the effects of non-surgical and surgical treatments? We searched: Medline, Embase, The Cochrane Library, and other important databases up to April 2009 (Clinical Evidence reviews are updated periodically; please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Results: We found 64 systematic reviews or RCTs that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions.

Conclusions: In this systematic review, we present information relating to the effectiveness and safety of the following interventions: acupuncture, analgesics, antidepressants, back schools, behavioural therapy, electromyographic biofeedback, exercise, injections (epidural corticosteroid injections, facet

joint injections, local injections), intensive multidisciplinary treatment programmes, lumbar supports, massage, muscle relaxants, non-steroidal anti-inflammatory drugs (NSAIDs), non-surgical interventional therapies (intradiscal electrothermal therapy, radiofrequency denervation), spinal manipulative therapy, surgery, traction, and transcutaneous electrical nerve stimulation (TENS).

(Copy of the summary available on request)

9. LEVEL 5: EXPERT OPINION

Percutaneous Treatment of Intervertebral Disc Herniation, Buy X, Gangi A, Semin Intervent Radiol. 2010 Jun; 27(2): 148–159.

Abstract

Interventional radiology plays a major role in the management of symptomatic intervertebral disc herniations. In the absence of significant pain relief with conservative treatment including oral pain killers and anti-inflammatory drugs, selective image-guided periradicular infiltrations are generally indicated. The precise control of needle positioning allows optimal distribution of steroids along the painful nerve root. After 6 weeks of failure of conservative treatment including periradicular infiltration, treatment aiming to decompress or remove the herniation is considered. Conventional open surgery offers suboptimal results and is associated with significant morbidity. To achieve minimally invasive discal decompression, different percutaneous techniques have been developed. Their principle is to remove a small volume of nucleus, which results in an important reduction of intradiscal pressure and subsequently reduction of pressure inside the disc herniation. However, only contained disc herniations determined by computed tomography or magnetic resonance are indicated for these techniques. Thermal techniques such as radiofrequency or laser nucleotomy seem to be more effective than purely mechanical nucleotomy; indeed, they achieve discal decompression but also thermal destruction of intradiscal nociceptors, which may play a major role in the physiopathology of discal pain. The techniques of imageguided spinal periradicular infiltration and percutaneous nucleotomy with laser and radiofrequency are presented with emphasis on their best indications.

Appendix 2 – Diagnostic and Procedure Codes

Out of contract spinal procedures GM018

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

GM018 - Out of Contract Spinal Procedures	
OPCS-4 Procedure Codes	
Primary laser foraminoplasty of lumbar spine	V56.3
Arthroscopic approach to joint (not needed for analysis) following V56.3	Y76.7
Revisional laser foraminoplasty of lumbar spine	V57.3
Arthroscopic approach to joint (not needed for analysis) following V57.3	Y76.7
Primary neurolysis of peripheral nerve and transposition of peripheral nerve	A68.1
Secondary neurolysis of peripheral nerve and transposition of peripheral nerve	A68.2
Neurolysis of peripheral nerve and transposition of peripheral nerve NEC	A68.3
Primary neurolysis of peripheral nerve NEC	A68.4
Secondary neurolysis of peripheral nerve NEC	A68.5
Other specified other release of peripheral nerve	A68.8
Unspecified other release of peripheral nerve	A68.9
Cryotherapy to organ NOC (secondary for all A68 codes)	Y11.2
Revision of neurolysis of peripheral nerve and transposition of peripheral nerve	A69.1
Destruction of intervertebral disc NEC	V52.2
Intervertebral disc of lumbar spine (secondary to V52.2)	Z99.3
Primary percutaneous intradiscal radiofrequency thermocoagulation to lumbar intervertebral disc	V62.3
Revisional percutaneous intradiscal radiofrequency thermocoagulation to lumbar intervertebral disc	V63.3
Approach to organ under fluoroscopic control (secondary to V62.3 and V63.3)	Y53.4
Primary automated percutaneous mechanical excision of lumbar intervertebral disc	V58.3
Revisional automated percutaneous mechanical excision of lumbar intervertebral disc	V59.3
Other specified primary excision of lumbar intervertebral disc	V33.8
Other specified revisional excision of lumbar intervertebral disc	V34.8
Laser excision of organ NOC (both Y08.1 and Y76.3 secondary to V58.3, V59.3, V33.8 or V34.8)	Y08.1
Endoscopic approach to other body cavity	Y76.3
With the following ICD-10 diagnosis code(s):	

Other specified intervertebral disc displacement	M51.2
Lumbar and other intervertebral disc disorders with myelopathy (G99.2*)	M51.0†
Myelopathy in diseases classified elsewhere (must be coded with M51.0D)	G99.2*
Lumbar and other intervertebral disc disorders with radiculopathy (G55.1*)	M51.1†
Nerve root and plexus compressions in intervertebral disc disorders (M50-M51†) - (must be coded with M51.1D)	G55.1*

Appendix 3 – Version History

Out of contract spinal procedures GM018

The latest version of this policy can be found here [GM Out of contract spinal procedures policy](#)

Version	Date	Summary of Changes
0.1		Initial draft
0.2	20/01/2016	Changes made to Policy following GM EUR Steering Group on 20 January 2016: <ul style="list-style-type: none"> • Commissioning Recommendation added. • Funding Mechanism added as Individual Prior Approval for Percutaneous endoscopic laser discectomy and percutaneous intradiscal laser ablation. • Wording for date of review changed Following the above changes the GM EUR Steering Group agreed the policy could go out for a period of clinical engagement.
	15/03/2016	Policy updated to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services.
1.0	20/07/2016	GM EUR Steering reviewed the clinical engagement feedback and agreed to amend the policy as follows: <ul style="list-style-type: none"> • Under Section 6 Evidence Summary the second paragraph on page 11 to read as follows: <i>"The evidence for percutaneous intradiscal laser ablation in the lumbar spine is limited but is supportive of its use in certain circumstances particularly as part of a clinical trial or audit. At present this procedure meets the Greater Manchester definition of experimental (unproven)."</i> • Typo error in the Commissioning Recommendation amend from local 'contacts' to read local 'contracts' Following the above changes the Greater Manchester EUR Steering Group agreed the policy could progress through the governance process.
1.1	08/12/2016	List of diagnostic and procedure codes in relation to this policy added as Appendix 2.
	07/03/2017	Approved by Greater Manchester Association Governing Group
	08/03/2017	Policy transferred to new template format.