



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# **Health Technology Assessment of Scheduled Procedures**

## **Spinal injections for pain due to degenerative lumbar spine disease**

**December 2013**

*Safer Better Care*



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The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

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- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.
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# **1 Spinal injections for pain due to degenerative lumbar spine disease**

## **1.1 Scope of this health technology assessment**

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral or treatment thresholds for spinal injections, a routine scheduled procedure within the publicly-funded healthcare system in Ireland. The effectiveness of spinal injections in the management of pain due to degenerative lumbar spinal disease may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled procedures. Details of the background to the request for the assessments from the Director General of the Health Service Executive (HSE), Mr Tony O'Brien, and the general methodology are included in the separate 'Background and Methods' document.<sup>(1)</sup>

The scope of this HTA is to investigate clinical referral and treatment thresholds for spinal injections for adults presenting with back pain in Ireland. Inputs from an Expert Advisory Group along with a review of the clinical and cost-effectiveness literature were used to inform the criteria. Additionally, the budget impact and resource implications were assessed, as appropriate.

## **1.2 Procedure indication**

Spinal injections are one type of minimally invasive interventional procedure used in managing (subacute, chronic, persistent or intractable) back pain either as an independent procedure or in conjunction with other modalities of care. Pain can occur in any region of the spine – cervical, thoracic, lumbar, or sacral, although low back pain (lumbosacral region) is the most common presenting complaint in the primary care setting. This scope of this HTA is limited to the use of spinal injections in the management of back pain due to degenerative lumbar spine disease.

Prevalence rates indicate that low back pain is a common problem affecting around one-third of the adult population each year,<sup>(2;3)</sup> particularly working-age adults, with peak incidence occurring in people aged between 25 and 64 years.<sup>(4)</sup> Low back pain can be divided into pain with a specific cause such as, but not limited to, spinal instability, spondylosis, spinal stenosis, discogenic back pain, disc herniation or prolapse, or due to non-specific chronic back pain for which a specific diagnosis is not possible. More than 85% of patients who present to primary care have low back pain that cannot reliably be attributed to a specific disease or spinal abnormality. Spinal stenosis and symptomatic herniated disc are present in about 3% and 4% of patients, respectively, while pain due to so called 'Red Flag' pathologies (e.g. cancer,

spinal infection, cauda equina syndrome) accounts for less than 1% of patients presenting in the primary care setting. The lumbosacral radicular syndrome, also called sciatica, is a disorder with radiating pain in the leg below the knee in one or more lumbar or sacral dermatomes, and can be accompanied by phenomena associated with nerve root tension or neurological deficits. A prolapsed disc is a frequent cause of sciatica, but other causes include spinal stenosis, tumours and radiculitis.<sup>(5)</sup>

Most episodes of low back pain will be short lived, with 80% to 90% of attacks resolving in about six weeks irrespective of the type of treatment administered and only 5% to 10% of patients developing persistent back pain.<sup>(6)</sup> The procedures referred to in this document are therefore only indicated in patients with persistent or disabling symptoms due to identified pathologies that do not settle with conservative measures, and for patients with chronic non-specific back pain who fail to respond adequately to initial conservative measures and who warrant referral for specialist review and management. Spinal injections have been used to alleviate low back pain due to a range of conditions including intervertebral disc herniation, spinal stenosis and discogenic pain without disc herniation or radiculitis;<sup>(7)</sup> the evidence to support their use is evaluated in detail in section 2.1.

The definition of chronic (or persistent) pain varies and a time cut-off is not always specified in guidelines.<sup>(8)</sup> The International Association for the Study of Pain (IASP) defines chronic pain as persisting beyond normal tissue healing time, assumed to be three months,<sup>(9)</sup> while the UK National Institute of Health and Care Excellence (NICE) defines chronic low back pain as pain, muscle tension or stiffness in the lower back region, with or without leg pain that persists for longer than six to twelve weeks.<sup>(2)</sup> The American Society of Interventional Pain Physicians defines chronic pain as 'a complex and multifactorial phenomenon with pain that persists six months after an injury and/or beyond the usual course of an acute disease or a reasonable time for a comparable injury to heal, that is associated with chronic pathologic processes that cause continuous or intermittent pain for months or years, that may continue in the presence or absence of demonstrable pathology and may not be amenable to routine pain control methods with healing never occurring'.<sup>(10;11)</sup>

Psychological and physical co-morbidities and risk factors are common in spinal pain.<sup>(6)</sup> There is extensive evidence associating chronic pain and psychopathology. Consequently, unrecognised and untreated psychopathology can interfere with the successful management of chronic pain and patient rehabilitation, be predictive of poor surgical outcomes, and may increase pain intensity and disability, thus serving to increase pain-related dysfunction, disability, and costs.<sup>(6)</sup> A multitude of physical

elements (including a lack of fitness, poor health, obesity, smoking, drug dependence, and other co-morbidities such as heart disease, diabetes and thyroid disease) also lead to increased morbidity and mortality in spinal pain patients.<sup>(6)</sup>

### **1.3 Procedure, potential complications and alternative treatments**

Spinal injections may be used for diagnostic or therapeutic purposes. Diagnostic injections are used to confirm the diagnosis and surgical pathology in patients with an equivocal diagnosis and/or involvement of multiple levels of the spine; this will usually precede another interventional procedure or surgery. Therapeutic spinal injections are used to provide symptom relief by targeting specific areas of the back that are potential sources of pain.<sup>(12)</sup> This is a very heterogeneous group of injections comprising different therapeutic agents that can be administered at a number of different sites. However, they can be broadly classified into two main types based on the site of the injection: epidural injections and facet joint injections (including intra-articular injections and facet joint nerve blocks). Typically, drugs administered via these injections will include a mix of corticosteroids and local anaesthetics. Depending on the indication, a single therapeutic spinal injection may provide some short-term pain relief, typically lasting less than three months in duration.<sup>(13)</sup>

Therapeutic spinal injections (hereafter referred to as spinal injections) may be considered as a treatment option in patients who have failed initial conservative management. This may have included: education and advice; medications delivered by conventional routes (including antidepressants, anticonvulsants, analgesics, non-steroidal anti-inflammatory drugs [NSAIDs] and opioids); acupuncture; physiotherapy including structured exercise programmes, manual therapies (including manipulation, massage and mobilisation) and transcutaneous electrical nerve stimulation (TENS); and psychological therapies (including cognitive behavioural therapy and supported self-management).<sup>(9;14;15)</sup> Clinical guidelines differ in their recommendations regarding initial conservative management<sup>(8)</sup> – recommendations in this regard are beyond the scope of this HTA. Surgical alternatives, which are indicated in patients requiring urgent management due to symptoms of focal neurological deficit, or patients with intractable pain unresponsive to other treatment modalities, include discectomy and decompression surgery, with or without spinal fusion.<sup>(11)</sup> Separate reports in this series of HTAs on scheduled procedures have been prepared for other interventional procedures for the management of chronic back pain, including surgical procedures and radiofrequency lesioning.



### **1.3.1 Epidural injections**

Access to the epidural space is available by caudal, interlaminar and transforaminal approaches. Due to the inherent differences between the approaches, they are associated with different advantages, disadvantages and clinical outcomes.<sup>(6;10)</sup> The caudal entry is viewed as the least complicated approach, with minimal risk of inadvertent dural puncture, but it requires the largest injection volume and is considered the least precise of the three approaches.<sup>(6)</sup> The interlaminar entry is directed more closely to the assumed site of pathology, requiring less volume than the caudal route.<sup>(6)</sup> The transforaminal approach is target specific, requires the least volume and is considered as the superior technique.<sup>(6)</sup> Selective transforaminal epidural injections are also known as selective nerve root blocks as they directly target the inflamed nerve root.

Good practice guidelines for the use of epidurals in the management of chronic spinal pain recommend these procedures are performed under fluoroscopic guidance to confirm the accurate placement of the epidural needle and the spread of the injectate.<sup>(16)</sup> Practice guidelines also strongly recommend that these interventional techniques are undertaken with meticulous aseptic technique in an environment that provides an appropriate level of asepsis, such as a sterile operating room or procedure room with appropriate monitoring equipment and facilities for resuscitation and post-procedure care.<sup>(6;17)</sup>

Complications of epidural injections predominantly relate to either needle placement or the drug administered.<sup>(6)</sup> Transient minor complications include: headache (28%), nausea, pruritis, increased pain of sciatic distribution.<sup>(4)</sup> Other reported complications include: dural puncture (0.3-0.5%), infection (1-2%), abscess formation, accidental subdural or intracranial air injection, epidural lipomatosis, pneumothorax, nerve damage, allergic reactions, seizures, osteonecrosis, osteoporosis, weight gain, pituitary suppression, increased intracranial pressure, intravascular injection (7.9-11.6%), vascular injury, cerebral vascular or pulmonary embolus and systemic effects of corticosteroids.<sup>(6;18;19)</sup> Although serious complications following epidural corticosteroid injection are rare, there are reports of blindness, paralysis, meningitis, brain damage, death, spinal cord trauma and spinal cord or epidural haematoma formation (0-1.9%) following injections.<sup>(6;10;12;18)</sup> Computed tomography (CT) and fluoroscopy-guided injections allow precise and safe needle placement during the procedures, but are associated with patient and operator exposure to ionising radiation.<sup>(19)</sup>

### 1.3.2 Facet joint injections

Facet joint injections include intra-articular injections and facet joint nerve blocks. Facet joints are well innervated by medial branches of the dorsal rami. Management of facet joint pain includes injection of local anaesthetics and, or corticosteroids into the facet joint (intra-articular injection) or close to the nerves supplying the joint (medial branch block or facet joint nerve block).<sup>(11)</sup>

Major complications with facet joint nerve blocks are rare. In a large prospective study of fluoroscopically-guided facet joint nerve blocks, the most common adverse event was local bleeding (72.7%) with oozing reported in 10.2% of cases. Other adverse events included intravascular penetration (4%), profuse bleeding (0.4%), bruising (0.3%), local haematoma (0.1%), nerve root irritation (0.1%), and vasovagal reactions (0.03%).<sup>(20)</sup>

Complications of intra-articular joint injections are rare, but can be serious. The most commonly reported complications include haematoma, corticosteroid side effects, accidental dural puncture and infection.<sup>(4)</sup> Other complications include: intra-arterial or intravenous injection, spinal anaesthesia, chemical meningitis, neural trauma, spinal cord injury, pneumothorax, radiation exposure and facet capsule rupture.<sup>(10)</sup> The use of fluoroscopic guidance during injections also adds risk due to radiation exposure, but as mentioned above is important to ensure accurate needle siting.<sup>(21)</sup>

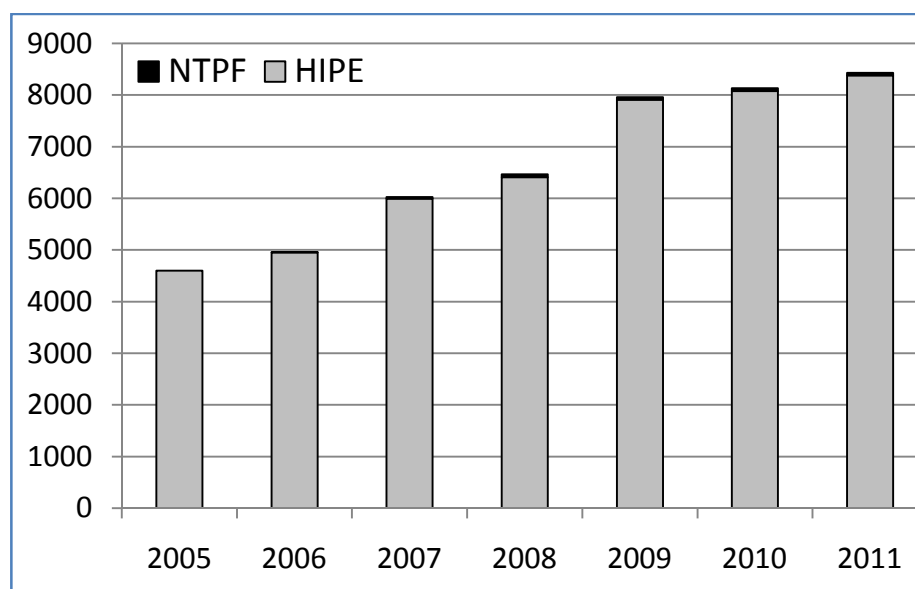
As noted in Section 1.3.1, evidence-based practice guidelines recommend that interventional spinal techniques are undertaken with meticulous aseptic technique in an environment that provides an appropriate level of asepsis, such as a sterile operating room or procedure room with appropriate monitoring equipment and facilities for resuscitation and post-procedure care.<sup>(6;6;17)</sup>

## 1.4 Current practice in Ireland

In 2011, data from the Hospital In-Patient Enquiry (HIPE) Scheme indicated that there were at least 8,379 discharges from public hospitals for patients who had undergone a spinal injection, as identified using the procedure codes specified in Appendix 1.<sup>(22)</sup> This data may underreport total activity as HIPE is limited to procedures provided in the inpatient and day case setting; interventions provided in the outpatient setting may therefore not be captured. Although the data do not permit episodes of care to be linked, repeat procedures are not uncommon, so that a patient may undergo a number of spinal injections during the course of a year. As noted, spinal injections may be for a diagnostic or therapeutic purpose; however, it is not currently possible to distinguish between the two in the HIPE data. Thus, the

numbers seen will overestimate those receiving spinal injections for therapeutic reasons. The majority of patients (89%) treated in 2011 were aged between 30 and 80 years. An additional 51 procedures were procured by the National Treatment Purchase Fund (NTPF) and performed in private hospitals, so that in total at least 8,430 procedures were provided by the publicly-funded healthcare system in 2011. The number of procedures provided through the publicly-funded healthcare system is increasing, with an 80% increase seen in procedure numbers between 2005 and 2011 (Figure 1.1 on the following page).

**Figure 1.1. Number of spinal injection procedures\* performed in public hospitals and purchased through the NTPF, 2005-2011<sup>(23)</sup>**



\* HIPE ICD-10AM/ACHI procedure blocks 32-37 and procedures 39013-00, 39013-01 and 40336-00, all procedures. Note: one individual may receive more than one spinal injection. HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.

Spinal injections are typically undertaken as a day case procedure with 89% of all cases performed as day case procedures in 2011, a rate that has been consistently high for several years. As previously noted, good practice guidelines recommend that therapeutic interventional procedures for chronic spinal pain should be performed using image guidance in an environment with clean air that provides an adequate level of asepsis. Spinal injections should therefore be provided in radiology suites or theatre settings rather than an outpatient department;<sup>(24)</sup> however, it is not known what portion of spinal injections are currently image-guided in the Irish healthcare system.

Spinal injections may be used for a number of different indications. Current data do not permit identification of the precise indication for which procedures are performed as the intervention and diagnosis codes are not linked. HIPE data capture the principal and up to 29 secondary diagnoses recorded in the patient medical notes for each episode of care. Diagnoses related to lumbar and sacral degenerative spinal disease accounted for over 75% of all principal diagnoses in 2011, with low back pain (54%) listed as the most common primary diagnosis. However, as noted, it is not possible to draw conclusions as to the precise indication for which the spinal injections were provided.

This procedure is mainly undertaken by pain specialists (47%) and orthopaedic surgeons (32%), with a smaller number undertaken by radiologists (8%) and anaesthetists (8%).<sup>(22)</sup> The procedure is widely available, with spinal injections provided in 35 hospitals in 2011. The spinal injection rate varies across the Health Service Executive (HSE) hospital groups announced by the Department of Health in May 2013 (Table 1.1).<sup>(25)</sup> There is also variation in the proportion treated as day cases, with Dublin East having a smaller proportion of day cases compared to other groups.<sup>(22;25)</sup> Data in relation to inpatient procedures should be interpreted with caution given that these incorporate interventions undertaken both as primary and secondary procedures (i.e. patient admitted for another reason and subsequently referred for a spinal injection) and the likelihood that the inpatient data is highly skewed by a small number of admissions.

**Table 1.1. HIPE data per HSE proposed hospital group\* (2011)**

Hospital group	Number (%)	ALOS (days)	Inpatient bed days	% day case	Avg. age (years)
Dublin North East	319 (4)	29.4	670	90.9	58.7
Dublin Midlands	1,290 (15)	9.7	1,273	93.4	47.1
Dublin East	2,380 (28)	17.9	4,276	79.2	58.5
South/South West	2,134 (26)	8.0	2,051	91.9	53.7
West/North West	1,472 (18)	8.2	716	93.6	57.0
Midwest	782 (9)	12.3	741	95.1	53.5
Acute paediatric services, Dublin	7 (1)	0	0	100.0	12.9

\* Data for hospitals included in the proposed hospital groups.<sup>(25)</sup> HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.

Standard practice in the publicly-funded healthcare system is that patients must be referred by their general practitioner (GP), or another consultant, to obtain a hospital outpatient appointment.<sup>(26)</sup> Suitability for surgery or other interventional procedures is based on clinical and radiological criteria.<sup>(5)</sup> In some instances the GP will refer patients for radiological imaging before attending a hospital outpatient appointment;

in other instances it is the hospital specialist who will refer the patient for imaging. Of note, international practice guidelines highlight that routine radiological imaging is not necessary in the management of low back pain in the primary care setting, except when serious underlying conditions are suspected on the basis of history or physical examination, and in patients with persistent signs or symptoms of radiculopathy or spinal stenosis who are potential candidates for surgery or other interventions.<sup>(5;8)</sup> Unless contra-indicated, the standard of care is for all patients to undergo MRI prior to spinal injection.<sup>(27)</sup> GPs report very limited direct access to MRI.<sup>(28)</sup> Timely access to MRI can also be problematic in the public system as demand, which is increasing with the expansion of the clinical indications for MRI, frequently exceeds capacity, leading to long waiting times in a number of hospitals. It has been reported that patients may independently choose to procure an MRI privately to expedite care, potentially increasing demand for outpatient specialist appointments.<sup>(29)</sup> National radiology referral guidelines are currently being finalised by the HSE's Radiology National Clinical Programme which include referral criteria for plain film X-ray and MRI.<sup>(30)</sup> Although these may help streamline referrals, it is recognised that there may be ongoing capacity issues with the requirement that access to MRI may be triaged based on clinical urgency.<sup>(31)</sup> While variability in image quality and reporting has been noted, it is imperative that every institution providing radiology services is compliant with guidelines developed by the National Quality Assurance Programme in Radiology.<sup>(30)</sup>

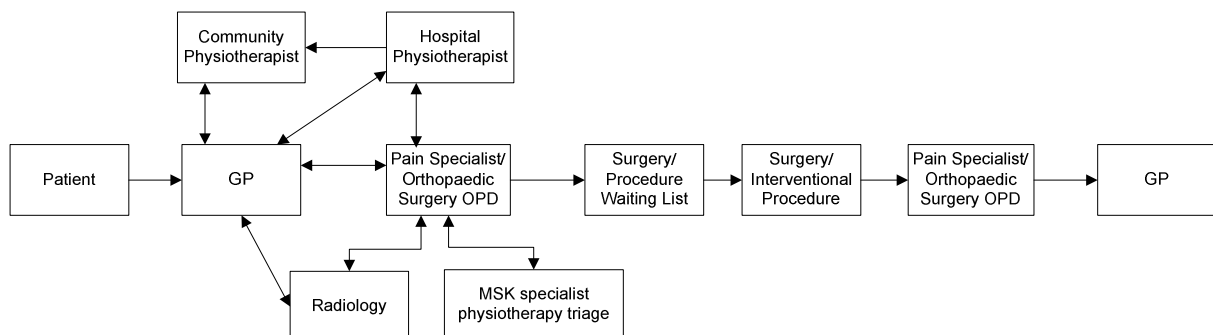
Patients who undergo spinal injections form a heterogeneous group, with a wide range of conditions and diagnoses. However, most patients with back pain due to lumbar degenerative spinal disease should first be offered structured conservative management which includes physiotherapy in the primary care setting. Referral for specialist review is then limited to those with 'Red Flag' symptoms that warrant urgent referral; patients that meet specific criteria such as spinal deformity, suspected spondylolisthesis or spondylolysis, or suspected rheumatological conditions; and patients who fail to respond adequately to structured conservative management including physiotherapy where appropriate. This is consistent with the model of care proposed in national policy frameworks<sup>(32)</sup> and international guidelines.<sup>(2)</sup> Access to physiotherapy in the primary care setting is reported to be limited within the publicly-funded system in Ireland, with the result that it appears that some patients are currently being referred without meeting this criterion.

Since March 2012, a triage scheme involving 24 specialist musculoskeletal (MSK) advanced practice physiotherapists has been in operation nationally (although not all hospitals) as a waiting list reduction initiative by the HSE's Orthopaedic and Rheumatology National Clinical Programmes. Under this scheme, patients who have

been referred to secondary care are initially triaged by the orthopaedic or rheumatology specialist, who can decide which patients are suitable for referral to an MSK physiotherapist for treatment; those whose symptoms persist following treatment are referred back to the consultant for specialist review, while those whose symptoms subside may be referred back to primary care. Although yet to formally report, anecdotally it is noted that only approximately 15%-20% of patients are referred back to the surgeon or rheumatologist for specialist assessment.<sup>(33)</sup> Separately, it has been reported in a retrospective review of data from a physiotherapy-led spinal triage clinic that 85% of patients referred to a spinal triage programme – with initial assessment and management by an MSK physiotherapist – were suitable for conservative management (defined as a 10-week evidence-based group education/exercise intervention or individual physiotherapy); 14% were discharged and only 1% required onward referral for specialist assessment.<sup>(34)</sup> Back pain triage clinics have also been established by some hospitals to facilitate timely access to appropriate services. These use stated referral criteria, standardised referral forms and triage processes for accessing orthopaedic, pain specialist, rheumatology and specialist physiotherapy services. It is recommended that unless urgent, patients access physiotherapy within the primary care system prior to referral to the triage clinic.<sup>(35)</sup> While the use of such stated criteria provide clarity, facilitate timely access and streamline the efficient use of resources, they do not eliminate wait times if need exceeds available capacity.

The current pathways for the referral, treatment and post-procedural follow up of patients in the publicly-funded healthcare system who cannot be adequately managed in the primary care setting, and who are referred for specialist review, subsequently undergoing spinal injections are illustrated in Figure 1.3.

**Figure 1.3. Current referral, treatment and follow-up pathways for publicly-funded patients receiving spinal injections**



Key: GP – general practitioner; OPD – outpatient department.

The length of time a patient must wait to be reviewed varies according to the referral pathway and the individual hospital and consultant to which a patient is referred. At the end of March 2013, it was reported that there were 384,632 patients on the Outpatient Waiting List database collated by the NTPF, 52% of whom were on the waiting list for less than six months with 73% on the list for less than 12 months.<sup>(36)</sup> It is noted that orthopaedic referrals constitute 10% of all outpatient referrals.<sup>(37)</sup> Within orthopaedics, it was reported that as of August 2013 there were 52,455 patients on the waiting list, 45% of whom were on the list less than six months and 67% on the list for less than 12 months.<sup>(38)</sup> Initiatives are underway by the HSE to standardise the management of outpatient services and to ensure that there are consistent management processes across all publicly-funded healthcare facilities that provide outpatient services. This includes the publication of a protocol for the management of these services by the NTPF in January 2013 which provides the core guidance of the Outpatient Services Performance Improvement Programme.<sup>(39)</sup> The protocol specifies that patients should be treated based on clinical urgency, with urgent referrals seen and treated first. It is intended that the definition of clinical urgency and associated maximum wait times is to be developed at specialty or condition level and agreed by the national clinical programmes.

In January 2013, the NTPF published a national waiting list management policy that outlines the standardised approach to managing scheduled care treatment for inpatient, day case and planned procedures in all publicly-funded hospitals. It outlines a consistent structured approach that must be adopted to the management of the waiting list; monitoring of the implementation of the policy will be routinely undertaken by the NTPF in the form of annual quality assurance reviews.<sup>(40)</sup> As of April 2013, a total of 1,028 people were on hospital waiting lists for spinal injections, with one in four people waiting over six months.<sup>(41)</sup> Based on data submissions from 44 hospitals, average patient waiting time for spinal injections was reported to range from less than a month to a maximum of 11 months.<sup>(37)</sup>

## **2 Clinical referral/treatment threshold**

### **2.1 Review of the literature**

A literature search was conducted during May 2013. The approach and general search terms are described in Appendix 1 in the separate 'Background and Methods' document accompanying this document. A summary of the results of this search is included in Table 2.1.

**Table 2.1. Included evidence sources.**

Publication Type	Number	References
Clinical guidelines	7	(4;7;10;11;13;15;42)
Health technology assessments	1	(43)
Systematic review	4	(44-47)
Cost-effectiveness studies	3	(43;48;49)

## 2.2 Clinical evidence

For spinal injection to be indicated, a patient should have failed a structured conservative management programme, and be clinically suitable for the procedure. As noted previously, clinical guidelines differ in their recommendations regarding what constitutes an effective structured conservative management programme,<sup>(8)</sup> however recommendations in this regard are beyond the scope of this HTA. Seven clinical guidelines relating to the adult population were found that specifically mention referral criteria for spinal injections (Appendix 2).<sup>(4;7;10;11;13;15;42)</sup> Within the National Health Service (NHS) in the UK, service delivery was until recently the responsibility of local primary care trusts (PCTs). Many PCTs set their reimbursement policy for spinal injections through the creation of defined clinical referral criteria. The PCTs were officially disbanded in March 2013 and their responsibilities taken over by Clinical Commissioning Groups (CCG) and the NHS Trust Development Authority. However, PCT thresholds are likely to represent ongoing clinical practice at a local level while new commissioning guides are being developed. Some examples of these referral thresholds are included in Appendix 2.

### 2.2.1 Epidural injections

According to the published guidelines, epidural injections are recommended for those with pain secondary to lumbar radiculopathy.<sup>(4;7;10;11;13;42)</sup> Radiculopathy is caused by compression or irritation of the nerves as they exit the spine and can be due to mechanical compression of the nerve by a disc herniation, a bone spur (osteophytes) from osteoarthritis, or from thickening of surrounding ligaments. Lumbar radiculopathy that causes pain that radiates down a lower extremity is commonly referred to as sciatica. There are a number of clinical trials and several systematic reviews that have evaluated the effectiveness of epidural corticosteroid injections for sciatica, however, the evidence of effectiveness is mixed.<sup>(10;12;43)</sup> Definitions of efficacy vary; however, a positive response is typically defined as significant pain relief and functional improvement of 50% or more as measured by validated pain



and disability scales. Efficacy has also been defined by duration of response, with an inability to achieve consistent pain relief for at least three weeks per procedure classified as treatment failure. Reasons for the discrepancies could be related to the choice of comparator treatment,<sup>(12)</sup> or the procedure itself, as in some of the systematic reviews caudal and interlaminar techniques were not considered separately.<sup>(10)</sup> Despite these inconsistencies, there is evidence that all three types of epidural corticosteroid injections – caudal, interlaminar and transforaminal – can provide pain relief in the short term (defined as less than six months).<sup>(4;6;10;11;13;43)</sup> However, there is only moderate evidence of their long-term (six months or more) effectiveness.<sup>(4;6;10-13)</sup>

Two of the published guidelines recommend caudal epidural injections for those with failed back surgery syndrome (FBSS).<sup>(10;11)</sup> The latest guideline recommendation is based on two randomised controlled trials (RCTs) showing positive outcomes for long-term relief, stating that it is the preferred modality of treatment based on fair evidence.<sup>(11)</sup> However, the evidence for transforaminal epidural injections in managing lumbar radicular pain in FBSS is limited.<sup>(11)</sup>

There is weaker and inconclusive evidence that epidural injections are effective for pain due to spinal stenosis,<sup>(6;10;12)</sup> with the latest guideline stating that the evidence is fair for caudal, interlaminar, and transforaminal epidural injections.<sup>(11)</sup>

Guidelines suggest that epidural injections should only be repeated if necessary, and provided that at least a 50% reduction in pain was obtained for two months. They note that there should be at least two months between each injection, with a maximum of four injections in one year.<sup>(11)</sup> Evidence for blind lumbar epidural injections (i.e. not image guided) is noted to be highly variable and consistently inferior to fluoroscopically-guided epidural injections.<sup>(50)</sup> As noted in Section 1.3, good practice guidelines recommended the use of image guidance to insure correct needle placement.

### **2.2.2 Facet-joint injections**

Updated clinical guidelines (2013) from the American Society of Interventional Pain Physicians (ASIPP) concluded that the evidence for therapeutic lumbar facet joint nerve blocks (using local anaesthetics with or without steroid) for managing chronic pain of facet joint origin is fair to good on the basis of two high quality studies and one moderate quality study, all of which were positive.<sup>(11)</sup> This is consistent with the findings of two recent systematic reviews which concluded (on the basis of the same trials) that the evidence was level II-1 or II-2<sup>(46)</sup> or fair to good for short- and long term improvement<sup>(47)</sup> of lumbar facet joint pain. Guidelines from Alberta (2011)

concluded that medial branch blocks may be beneficial for carefully selected patients with a clinical diagnosis of pain originating from the lumbar facet joints with studies showing benefit for up to six weeks and sometimes longer.<sup>(4)</sup>

Guidelines suggest that therapeutic facet joint nerve blocks should be repeated only as necessary according to the medical criteria, with at least two months between injections, and provided at least a 50% reduction in pain is obtained for two months. During the treatment phase, it is suggested that the number of procedures should be limited to a maximum of four blocks per region, over a period of one year.<sup>(11)</sup>

According to one of the published guidelines (Alberta 2011), intra-articular injections are recommended for those with pain originating from the lumbar facet joint.<sup>(4)</sup> Updated guidelines (2013) from the ASIPP however concluded that based on one moderate quality study with weakly positive or undetermined results and five observational studies the evidence for intra-articular injections for facet joint pain is limited. The guidelines also noted negative findings for one high quality randomised, double-blind trial at six months and for one non-randomised, observational trial.<sup>(11)</sup> This was consistent with the findings of a systematic review published in 2012 by Falco et al..<sup>(47)</sup>

It is argued that the outcomes of facet joint interventions depend on the accuracy of the diagnosis: a confirmed diagnosis of facet joint pain can be achieved with reasonable certainty only on the basis of controlled diagnostic local anaesthetic blocks, as these are inherently non-specific.<sup>(6;47)</sup> The updated 2013 guidelines from the ASIPP note that recommendations for therapeutic facet joint injections are based on a diagnosis that has been established by a positive response (75% reduction in pain with ability to perform prior painful movements without significant pain) to controlled diagnostic blocks.<sup>(11)</sup>

Intra-articular facet joint injections for the management of chronic non-specific low back pain have been consistently found to be ineffective and of little value.<sup>(6;12;15)</sup> As a result, many health insurers no longer cover this treatment indication.<sup>(50;51)</sup>

### **2.3 Cost-effectiveness evidence**

The direct and indirect financial costs of back pain are substantial in all developed countries.<sup>(15)</sup> When compared to surgical intervention, all types of epidural injections (caudal, transforaminal and interlaminar) for chronic low back pain have been found to be cost-effective due mainly to the avoidance of surgical intervention.<sup>(6;10)</sup> In 2013, Manchikanti et al. reported on a cost-utility analysis of caudal epidural injections in the treatment of lumbar disc herniation, axial or discogenic low back pain, central

spinal stenosis, and post-lumbar surgery syndrome based on four previously published RCTs (n=480 patients).<sup>(48)</sup> They concluded that caudal epidural injections in the treatment of disc herniation, axial or discogenic low back pain, central spinal stenosis, and post-surgery syndrome in the lumbar spine had a cost-utility at less than US\$2,200 per one year of QALY. Lewis et al.<sup>(43)</sup> developed an economic model which followed a stepped approach to treatment for sciatica and found epidural injections to be a cost-effective treatment option. Whynes et al.<sup>(49)</sup> assessed the cost-effectiveness of injections administered in a routine outpatient setting in England and found that when provided in an outpatient setting, epidural steroid injections are a short-term, but nevertheless cost-effective, means of managing chronic low back pain.

## 2.4 Budget impact and resource implications

Without any clear guidance on referral criteria in place for spinal injections in Ireland, there is inevitably variation in referral and treatment patterns. There is no evidence of inappropriate procedures taking place. However, there is evidence of regional variation in treatment numbers and the proportion of patients treated as day cases. Best practice is that spinal injections should be image-guided to ensure correct needle placement, therefore, injections should be administered in settings with radiology imaging by trained specialists. It is not known if there is variation in the use of image-guidance or in the type of spinal injection administered (epidural or facet joint) or the epidural approach used (caudal, interlaminar or transforaminal).

HIPE data indicate an 80% increase in the use of spinal injections since 2005. This is consistent with international trends, with reports of over a 100% increase in the use of minimally invasive spinal interventions, including spinal injections for pain management over the same time period.<sup>(52;53)</sup> The current estimated annual national cost of spinal injections is €13.1 million, based on the latest Casemix costs (Table 2.2). This may be an overestimate as it includes admissions where the spinal injection was not the principal procedure.

**Table 2.2. HSE inpatient and day case acute hospital activity and costs summarised by diagnosis-related group (based on 2011 costs and activity)\*<sup>(54)</sup>**

DRG code	Description	% of spinal injection procedures	Cost/inpatient (€)	Cost/day case (€)
I68C	Non-surgical spinal disorders; same day	82%	202	581
I71B	Other musculotendinous disorders W/O Catastrophic or	3%	2,056	442

	severe CC			
I68B	Non-surgical spinal disorders W/O CC	2%	2,214	581
I68A	Non-surgical spinal disorders W CC	1%	6,444	581
-	Other procedures**	12%	-	-
-	Outpatient appointment	-	-	130

*\*Data summary from HSE National Casemix Programme Ready Reckoner, 2013 based on the 2011 inpatient and day case activity and costs reported by 38 hospitals participating in the programme that year.*

*\*\* Note: the remaining diagnosis-related groups accounted for 2% or fewer of the procedures.*

### 3 Advice on clinical referral/treatment threshold

The current international guidelines and evidence suggest that spinal injections should only be considered after conservative management has been exhausted and then only for a number of defined indications. There is no clear evidence on the optimal timeline for referral. Consistent with evidence-based good practice guidelines, all interventional spinal procedures should be performed using image-guidance to ensure correct needle placement and spread of the injectate. Procedures should be undertaken with meticulous aseptic technique in an environment that provides an appropriate level of asepsis, such as a sterile operating room or procedure room with appropriate monitoring equipment and facilities for resuscitation and post-procedure care.<sup>(6;17)</sup> The following criteria are advised:

Note: these criteria only apply to adult patients with lumbar back pain.

The decision to refer a patient for a spinal injection should be based on consideration of their clinical symptoms, and their potential for functional benefits.

An epidural injection is justified and appropriate for lumbar back pain in the following situations:

- failure of an improvement in symptoms following conservative management (including physiotherapy) **AND**
- clinical symptoms and diagnostic imaging compatible with radiculopathy due to a prolapsed disc **OR**
- clinical symptoms and diagnostic imaging compatible with failed back surgery syndrome.

A facet joint nerve block is justified and appropriate for lumbar back pain in the following situations:

- failure of an improvement in symptoms following conservative management (including physiotherapy) **AND**
- clinical symptoms and results from a controlled diagnostic block compatible with pain originating at the facet joint.

There is limited evidence for intra-articular injections for lumbar facet joint pain. Facet joint injections are not recommended for the management of non-specific chronic back pain.

A patient should not be referred for spinal injections if:

- the patient's quality of life or ability to function is not compromised.

Patients who are not referred for a spinal injection should remain under the care of their primary care practitioner (GP, community physiotherapist) and be reassessed as appropriate.

## **4 Discussion**

Epidural spinal injections have been shown to be an effective additional treatment to conservative management for individuals with radiculopathy due to a prolapsed disc, while epidural injections using a caudal approach have been noted to be effective for those with failed back surgery syndrome. Facet joint nerve blocks may be effective for those with pain originating at the facet joint, however evidence to support the use of intra-articular injections for this indication is limited. Of note, evidence to support the use of blind lumbar epidural injections (i.e. not image guided) is noted to be highly variable and consistently inferior to fluoroscopically-guided injections. Good practice guidelines for the use of epidurals in the management of chronic spinal pain recommend these procedures should be performed under fluoroscopic guidance to confirm the accurate placement of the epidural needle and the spread of the injectate. Spinal injections may provide only temporary relief with patients often requiring repeat injections to maintain pain relief and functional improvement, thus careful management of patient expectations and continued primary care management is essential. Careful assessment of both the level of patient response (using validated pain and disability scales) and an adequate duration of response should be used to justify repeat interventions.

Currently in Ireland most patients will experience a waiting time, which may be substantial, before being seen in an outpatient clinic and subsequently before receiving a spinal injection. Without any clear referral criteria in place in Ireland for spinal injections, this has inevitably led to variation in the referral and treatment patterns.

The number of therapeutic spinal injections performed in the publicly-funded system is not expected to reduce as a result of implementing stated treatment thresholds. HIPE data indicate an 80% increase in the number of spinal injections administered since 2005, and consistent with international data, a trend towards increased use of spinal injections as a treatment modality may continue. However, the use of spinal

injections is not without risks, and there is evidence of variability in efficacy depending on the approach used and the therapeutic indication. The aim of standardised referral and treatment criteria is to ensure that all patients receive the right care, at the right time and in the right setting. As mentioned in section 1.4, there is some evidence of regional variation which may indicate differences in access or clinical practice. Implementing standardised referral and treatment criteria may reduce this variation, help to ensure transparency, enable audit to take place and may allow for the more efficient use of available resources by ensuring that patients are triaged and receive appropriate primary and specialist care in a timely fashion.

A caveat to the effective implementation of referral thresholds in Ireland is the limited access to conservative management (physiotherapy) in the primary care setting. Of note, initiatives are underway by the Orthopaedic and Rheumatology National Clinical Programmes in the HSE to develop interface clinics and consultations between primary and secondary care services in Ireland and to implement agreed national referral guidelines for all patients with musculoskeletal disease. Definition of what structured conservative management should comprise and the duration of this intervention would help clarify what constitutes an adequate course of structured conservative management. This should help to ensure that patients who do not meet the criteria for surgery or other interventional procedures have timely access to appropriate high quality care in the primary care setting, while patients who have had an inadequate response or who have failed to respond to conservative management obtain a timely referral for specialist review.

The suggested referral criteria reflect existing best practice in Ireland. Consistent application of the criteria throughout the healthcare system through the use of stated thresholds that are integrated into agreed national referral guidelines should assist patient triage, bring greater transparency, ensure equity of access based on clinical need and allow maximal benefit to be gained from existing resources. Consistent with best practice, guidelines and thresholds should be updated as necessary to reflect changes in the evidence base. Finally, as outlined in the ethical analysis report, if clinical referral or treatment thresholds are implemented, it is imperative that there are opportunities for appeal to ensure good governance.

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## Appendix 1 – HIPE ICD-10AM intervention codes for spinal injections

Block	Procedure code	Description
31	39013-00	Administration of agent into zygo-apophyseal (facet) joint
	39013-01	Administration of agent into costotransverse joint
	40336-00	Administration of chemonucleolytic agent into disc
32	18216-27	Epidural injection of local anaesthetic
	18216-28	Epidural injection of opioid
	90028-00	Epidural injection of steroid
	90018-00	Epidural injection of other or combined therapeutic substance(s)
	18230-00	Epidural injection of neurolytic agent
	39140-00	Epidural injection for lysis of adhesions
33	18216-00	Epidural infusion of local anaesthetic
	18216-03	Epidural infusion of opioid
	90028-01	Epidural infusion of steroid
	18216-06	Epidural infusion of other or combined therapeutic substance(s)
34	18216-29	Caudal injection of local anaesthetic
	18216-30	Caudal injection of opioid
	90028-02	Caudal injection of steroid
	90019-00	Caudal injection of other or combined therapeutic substance(s)
35	18216-09	Caudal infusion of local anaesthetic
	18216-12	Caudal infusion of opioid
	90028-03	Caudal infusion of steroid
	18216-15	Caudal infusion of other or combined therapeutic substance(s)
36	18216-31	Spinal injection of local anaesthetic
	18216-32	Spinal injection of opioid
	90028-04	Spinal injection of steroid
	90020-00	Spinal injection of other or combined therapeutic substance(s)
	18230-01	Spinal injection of neurolytic agent
37	18216-18	Spinal infusion of local anaesthetic
	18216-21	Spinal infusion of opioid
	90028-05	Spinal infusion of steroid
	18216-24	Spinal infusion of other or combined therapeutic substance(s)

## Appendix 2 – Examples of international clinical referral thresholds

Guideline	Scope	Spinal injections	Evidence
American Society of Interventional Pain Physicians (ASIPP)(2013) US <sup>(11)</sup>	<b>Indications:</b> Chronic spinal pain <b>Population:</b> Not specified	<u>Lumbar Spine: Therapeutic Epidural Injection</u> The evidence for caudal epidural, interlaminar, and transforaminal epidural injections is good in managing disc herniation or radiculitis; 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 injections. The recommendation for epidural injections for disc herniation is that one of the 3 approaches may be used; for spinal stenosis any of the 3 approaches are recommended; whereas for axial or discogenic pain either lumbar interlaminar or caudal epidural injection are recommended. However, for transforaminal the evidence is limited for axial or discogenic pain and post surgery syndrome.  <u>Therapeutic Lumbar Facet Joint Interventions</u> The evidence for lumbar conventional radiofrequency neurotomy is good, limited for pulsed radiofrequency neurotomy, fair to good for lumbar facet joint nerve blocks, and limited for intraarticular injections. Among the therapeutic facet joint interventions either conventional radiofrequency neurotomy or therapeutic facet joint nerve blocks are recommended after the appropriate diagnosis with controlled diagnostic lumbar facet joint nerve blocks.	<b>Literature review:</b> Systematic review <b>Grading system:</b> Developed own system based on various publications <b>Key references:</b> See report
Toward Optimized Practice (2011) Alberta, Canada <sup>(4)</sup>	<b>Indications:</b> Acute and sub-acute low back pain, Chronic low back pain Acute and sub-acute, sciatica/radiculopathy, Chronic sciatica/radiculopathy <b>Population:</b> Adults	The following injection therapies may be beneficial for carefully selected patients with a clinical diagnosis of pain originating from the lumbar facet joints: <ul style="list-style-type: none"> <li>• intra-articular facet joint blocks</li> <li>• medial branch blocks (studies show benefit for up to six weeks and sometimes longer)</li> <li>• medial branch neurotomy (studies demonstrate pain relief lasting longer than three months)</li> </ul> The clinical diagnosis of facet joint pain lacks specificity and may be best determined by a trained spinal care specialist.  For patients with leg pain, epidural steroid injections can be effective in providing short-term and occasional long-term pain relief. Fluoroscopy improves/verifies accuracy. Even in the most experienced hands, epidural injections can be misplaced.  <b>Exclusions:</b> pregnant women; patients <18 years; diagnosis or treatment of specific causes of low back pain such as: inpatient treatments ( surgical treatments); referred pain (from abdomen, kidney,	<b>Literature review:</b> Systematic <b>Grading system:</b> SIGN scale <b>Key references:</b> Chronic pain management: guidelines for primary care practice in the Calgary Health Region. 2005.  Low back pain: evidence-based clinical practice guidelines for primary care practice in

		ovary, pelvis, bladder); inflammatory conditions (rheumatoid arthritis, ankylosing spondylitis); infections (neuralgia, discitis, osteomyelitis, epidural abscess); degenerative and structural changes (spondylosis, spondylolisthesis, gross scoliosis and/or kyphosis); fracture; neoplasm; metabolic bone disease (osteoporosis, osteomalacia, Paget's disease).	the Calgary Health Region – chronic pain services in the community: supporting primary care. 2006
NICE CG88 (2009) UK <sup>(2)</sup>	<b>Indications:</b> Non-specific low back pain <b>Population:</b> Adults with low back pain for >6 weeks and <12 months	Do not offer injections of therapeutic substances into the back for non-specific low back pain. <b>Exclusions:</b> malignancy, infection, osteoporotic collapse, fracture, ankylosing spondylitis or other inflammatory disorders, sciatica and cauda equina syndrome, children <18 years, people with acute low back pain (<6 weeks duration), people with non-specific low back pain of >12 months duration	<b>Literature review:</b> Systematic <b>Grading system:</b> NICE <b>Key references:</b> Boswell et al., Crette et al., Dagenais et al., Khot et al.
American Pain Society (2009) US <sup>(10)</sup>	<b>Indications:</b> Persistent (at least subacute in duration) low back pain <b>Population:</b> Adults	In patients with persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy and intradiscal corticosteroid injection are not recommended.  There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or intrathecal therapy with opioids or other medications for nonradicular low back pain.  In patients with persistent radiculopathy due to herniated lumbar disc, it is recommended that clinicians discuss risks and benefits of epidural steroid injection as an option. It is recommended that shared decision-making regarding epidural steroid injection include a specific discussion about inconsistent evidence showing moderate short-term benefits and lack of long-term benefits. There is insufficient evidence to adequately evaluate benefits and harms of epidural steroid injection for spinal stenosis.  The guideline is not intended to guide evaluation or management of patients with back pain associated with major trauma, tumour, metabolic disease, inflammatory back disease, fracture, dislocation, major instability, or major deformity; patients with progressive or severe neurologic deficits; children or adolescents with low back pain; pregnant women, patients with low back pain from sources outside the back (non-spinal low back pain) and thoracic or cervical spine pain.	
American Academy of Neurology (2007) US <sup>(13)</sup>	<b>Indications:</b> Radicular Lumbosacral Pain <b>Population:</b> Adults	Epidural steroid injections may result in some improvement in radicular lumbosacral pain when determined between two and six weeks following the injection, compared to control treatment.  In general, epidural steroid injections for radicular lumbosacral pain have shown no impact on	<b>Literature review:</b> Systematic

		<p>average impairment of function, on need for surgery, or on long-term pain relief beyond three months. Their routine use for these indications is not recommended.</p> <p>Data on use of epidural steroid injections to treat cervical radicular pain are inadequate to make any recommendation.</p>	
British Society for Rheumatology (2001) UK <sup>(42)</sup>	<p><b>Indications:</b> Spinal pain</p> <p><b>Population:</b> Adults</p>	Epidural steroid injections are an evidence-based treatment for sciatica.	

Study	Description	Sample size (n)	Finding
Spiker et al 2012 <sup>(45)</sup>	Systematic review	12 studies	This systematic review compared outcomes of surgical intervention with therapeutic injection for the treatment of chronic sacroiliac joint pain. They concluded that surgical fusion and therapeutic injections can likely provide pain relief, improve quality of life and improve work status, however the comparative effectiveness of these interventions cannot be evaluated with the current literature.
Jacobs et al 2011 <sup>(44)</sup>	Systematic review		This study assessed the effects of surgery versus conservative therapy (including epidural injections) for patients with sciatica due to lumbar disc herniation. Five studies were identified, two of which with a low risk of bias. One study compared early surgery with prolonged conservative care followed by surgery if needed; three studies compared surgery with usual conservative care and one study compared surgery with epidural injections. One large low-risk-of-bias trial demonstrated that early surgery in patients with six to twelve weeks of radicular pain leads to faster pain relief when compared with prolonged conservative treatment, but there were no differences after one and two years. Another large low-risk-of-bias trial between surgery and usual conservative care found no statistically significant differences on any of the primary outcome measures after one and two years.
Lewis et al 2011 <sup>(43)</sup>	Health technology assessment		This HTA investigated the clinical and cost-effectiveness of different management strategies for sciatica by undertaking a systematic review and an economic evaluation. They found support for the effectiveness of currently used therapies for sciatica, such as non-opioid medication, epidural corticosteroid injections and disc surgery, but also for chemonucleolysis, which is no longer used in the UK NHS. In addition, they did not find support for the clinical effectiveness of opioid analgesia, which is widely used in this patient group. They also suggest that less frequently used treatments, such as acupuncture and experimental treatments, such as anti-inflammatory biological agents, may be effective. In terms of cost-effectiveness, the argument for stepped approaches based on an initial treatment with non-opioids, as opposed to direct referral for surgery, was apparent.



Examples of UK PCT thresholds	Scope	Threshold	Evidence
Bath and North East Somerset	<p><b>Indications:</b> Epidural injection in management of back pain</p> <p><b>Population:</b> Adults</p>	<p>The PCT will fund <b>lumbar interlaminar</b> and <b>lumbar transforaminal</b> epidural injections for patients with radicular pain due to herniated disc (sciatica) when the following criteria have been met:</p> <ul style="list-style-type: none"> <li>• Symptoms persist despite some conservative management for at least three months.</li> <li>• The patient is 18 years or above.</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• There is evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise–positive between 30° and 70° or positive femoral tension sign);</li> </ul> <p>To prevent complications associated with steroids patients may receive up to three injections in 12 months two to three months apart provided there has been &gt;50% reduction in symptoms for six weeks.</p> <p><b>Caudal epidural injections</b> There is insufficient evidence for the use of caudal epidural injections in the management of spinal pain.</p>	<p><b>Key references:</b></p>

	<p><b>Indications:</b> Facet joint injections in management of back pain</p> <p><b>Population:</b> Adults</p>	<p>PCT will fund the specific facet joint injections as specified below:</p> <ul style="list-style-type: none"> <li>• <b>Intraarticular injections</b> for the management of somatic or nonradicular pain of lumbar origin.</li> <li>• <b>Medial branch blocks</b> for the management of somatic or nonradicular pain of cervical, thoracic and lumbar back origin.</li> </ul> <p>PCT will fund facet joint injections when all the following criteria are met:</p> <ul style="list-style-type: none"> <li>• Facet joint pain is confirmed by controlled diagnostic local anaesthetic block.</li> <li>• The pain has lasted for more than three months and average pain levels of <math>\geq 6</math> on a scale of 0 to 10. Levels of pain must be assessed using a validated tool, e.g. McGill Pain Questionnaire, Pain VAS.</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• The pain has resulted in significant impact on daily functioning.</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• All conservative management options have been tried for at least three months and failed.</li> <li>• Therapeutic facet joint injections beyond the first three injections are provided as part of a comprehensive pain management programme.</li> </ul> <p>In the diagnostic phase the patient may receive two injections one to two weeks apart, in the therapeutic phase, up to three injections two to three months apart provided there has been &gt;50% reduction in symptoms for eight weeks.</p> <p>PCTs will fund <b>cervical facet joints</b> (medial branch neurotomy) in the following circumstances:</p> <ul style="list-style-type: none"> <li>• patients aged over 18</li> <li>• non-radicular lumbar (all levels) or cervical (C3-4 and below) facet joint pain</li> <li>• failure of six months of non-invasive therapy, such as medication and physiotherapy and bed rest</li> <li>• average pain levels of <math>\geq 6</math> on a scale of 0 to 10. Levels of pain must be assessed using a validated tool, e.g. McGill Pain Questionnaire, Pain VAS</li> <li>• radiological imaging to rule out any correctable structural lesion, e.g. MRI</li> <li>• 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 80% 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</li> <li>• all procedures must be performed under fluoroscopy (X-ray guidance).</li> </ul> <p>PCTs will fund one injection per side per level i.e. 1 facet neurotomy at the same side at the same level or two joint levels unilaterally or bilaterally. PCTs will not fund retreatment at the same location unless at least 6 months have elapsed since prior treatment.</p> <p>If more than one region are involved all regions be treated at the same time, provided all procedures are performed safely. Cervical and thoracic are considered as one region and lumbar and sacral are considered as one region.</p>	
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<p>Bedfordshire and Hertfordshire</p>	<p><b>Indications:</b> Persistent non-specific low back pain <b>Population:</b> Adults</p>	<p>NICE guidance recommends that the following treatments should not be offered for the early management of persistent non-specific low back pain:</p> <ul style="list-style-type: none"> <li>• selective serotonin reuptake inhibitors (SSRIs) for treating pain</li> <li>• injections of therapeutic substances into the back</li> <li>• laser therapy</li> <li>• interferential therapy</li> <li>• therapeutic ultrasound</li> <li>• TENS</li> <li>• lumbar supports</li> <li>• traction.</li> </ul>	<p><b>Key references:</b> Bigos S et al. 1994, Van der Heijden et al. 1995, Van Tulder et al. 2004, NICE CG88 2009</p>
<p>Bedfordshire and Hertfordshire</p>	<p><b>Indications:</b> Spinal / Epidural Injection <b>Population:</b> Adults</p>	<p>Unless all of the following criteria are met, spinal/epidural Injection will not normally be funded:</p> <ul style="list-style-type: none"> <li>• Pain lasting more than six weeks but less than 12 months.</li> <li>• Maximum oral and topical analgesia have failed.</li> <li>• A Clinician trained in back pain assessment, diagnosis and management has assessed the patient and considers it would enable mobilisation and participation in rehabilitation. It is a dedicated physiotherapy based mobilisation programme, i.e. the intervention is intended to enable mobilisation and participation in rehabilitation (they will not be funded as stand-alone treatments).</li> </ul> <p>No more than two injections sessions ( facet joint) will be funded.</p>	
<p>Birmingham East and North</p>	<p><b>Indications:</b> Epidural injections for sciatica, femoralgia and symptomatic spinal stenosis <b>Population:</b> Adults</p>	<p>The PCTs will fund cervical, thoracic and lumbar (interlaminar, transforaminal and caudal) epidural injections only for patients with radicular pain which has lasted less than six months when the following criteria have been met:</p> <ul style="list-style-type: none"> <li>• The patient has radicular pain consistent with the level of spinal involvement based on clinical assessment.</li> <li>• The patient is 18 years or above.</li> </ul> <p>AND</p> <ul style="list-style-type: none"> <li>• Symptoms persist despite some conservative management for at least four weeks.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• Symptoms are severely disabling or have required or are likely to require hospitalisation due to pain and immobility despite maximum tolerated analgesia.</li> </ul>	<p><b>Key references:</b> NICE CC 88 2009</p>

	<p>Patients may routinely receive up to three therapeutic injections provided there has been a clinical response and a further two diagnostic transforaminal injections in patients where surgery is being considered. Epidural injections are funded only when provided as part of a comprehensive pain management pathway (including appropriate analgesia, physiotherapy and exercise advice).</p> <p>The PCTs will fund cervical, thoracic and lumbar (interlaminar, transforaminal and caudal) epidural injections only for patients with radicular pain which has lasted more than six months when the following criteria have been met:</p> <ul style="list-style-type: none"> <li>• The patient has radicular pain consistent with the level of spinal involvement.</li> <li>• The patient is 18 years or above.</li> <li>• All conservative management options (exercise, pharmacotherapy including analgesia, anti-inflammatories and psychotropic medication) have been tried and failed.</li> </ul> <p>Patients may routinely receive up to three injections at least three months apart over a one-year period provided there has been clinically meaningful improvement when assessed at three months following the injection.</p> <p>Epidural injections are funded only when provided as part of a comprehensive pain management pathway as defined below.</p> <p>Additional epidural injections will not normally be funded other than in a sub-group of patients for whom long-term epidural treatment may be a cost-effective option and where patients meet the following criteria:</p> <ul style="list-style-type: none"> <li>• There is clinically meaningful improvement when assessed at three months following injection (two-point improvement on a VAS or either much improved or very much improved on the PGIC) and this enables patients to demonstrate significant improvement in function in relation to activity of daily living, e.g. improvement in Oswestry Disability Index &gt;8, or Roland Morris Disability Questionnaire &gt;5.</li> <li>• Patients have demonstrated commitment to a comprehensive pain management plan including: increased fitness through exercise and physiotherapy; lifestyle changes (such as weight loss, diet control, avoidance of illicit drugs and alcohol and improvement in sleep patterns); managing mood and mental health; and improved engagement in activities of daily living and purposeful occupation where appropriate</li> <li>• Surgery is not the preferred option.</li> <li>• The decision to continue treatment with epidurals has been discussed and agreed at a MDT meeting.</li> </ul> <p>For this sub-group of patients the PCTs will fund a maximum of two epidurals per year whilst they continue to fulfil the criteria above.</p>	
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	<p><b>Indications:</b> Therapeutic Facet Joint Injections</p> <p><b>Population:</b> Adults</p>	<p>The PCTs will fund either medial branch blocks or intra-articular facet joint injections for the management of cervical, thoracic and lumbar spinal pain when the following criteria are met:</p> <ul style="list-style-type: none"> <li>• The pain has resulted in moderate to significant impact on daily functioning.</li> <li>• All conservative management options (exercise, pharmacotherapy including analgesia, anti-inflammatories and psychotropic medication) have been tried and failed.</li> <li>• Facet joint injections are funded only when provided as part of a comprehensive pain management pathway as defined below.</li> </ul> <p>The patient may receive up to three injections over a one-year period provided there has been clinically meaningful improvement when assessed at three months following the injection. Patients who have clinically meaningful benefit on two consecutive occasions should be considered for a facet joint denervation.</p> <p>The PCTs will continue to fund facet joint injections in a defined clinical sub-group of patients when the following criteria have been met:</p> <ul style="list-style-type: none"> <li>• All possible alternative approaches have been tried and have failed</li> <li>• Patients have demonstrated commitment to a comprehensive pain management plan including: increased fitness through exercise and physiotherapy; lifestyle changes (such as weight loss, diet control, avoidance of illicit drugs and alcohol and improvement in sleep patterns); managing mood and mental health; and improved engagement in activities of daily living and purposeful occupation where appropriate</li> <li>• The decision to continue treatment with facet injections has been discussed and agreed at a MDT meeting.</li> </ul>	
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<p>NHS Bournemouth and Poole and NHS Dorset</p>	<p><b>Indications:</b> Chronic Lumbar conditions <b>Population:</b> Adults</p>	<p>Lumbar epidural, caudal, interlaminar, transforaminal, intra-articular facet and sacroiliac joint steroid injections; lumbar medial branch blocks and lumbar intradiscal injections with methylene blue are NOT recommended for the treatment of following:</p> <ul style="list-style-type: none"> <li>• Low back pain with sciatica or radiculopathy.</li> <li>• Low back pain without sciatica or radiculopathy.</li> <li>• Spinal Stenosis.</li> <li>• Failed back surgery syndrome.</li> <li>• Disc prolapse or discogenic back pain.</li> <li>• Confirmed and presumed facet joint pain.</li> <li>• Facet joint osteoarthritis.</li> <li>• Non radicular back pain.</li> <li>• Sacroiliac joint pain.</li> </ul> <p>Cervical spinal epidural injections, facet joint injections and medial branch blocks are NOT recommended for the following:</p> <ul style="list-style-type: none"> <li>• Neck pain with disc herniation and radiculitis.</li> <li>• Neck pain without disc herniation.</li> <li>• Disc compression and radiculitis.</li> <li>• Confirmed facet joint pain.</li> </ul> <p>Spinal injections are NOT recommended for non-specific low back pain.</p> <p>Patients with acute radiculopathy may benefit from a nerve root block. Patients need careful selection.</p> <p>This policy refers to chronic back pain and does not include acute back pain conditions such as fracture, dislocation, complications of tumour or infection and/or nerve root or spinal compression responsible for progressive neurological deficit. This policy does not cover some of the causes of chronic back pain such as osteoporosis and related compression fractures, lumbar spine arthritis, infection, tumour, sagittal imbalance and spinal deformity.</p>	<p><b>Key references:</b> NICE CC 88 2009</p>
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