NHS
Vale of York
Clinical Commissioning Group

04. Therapeutic and diagnostic injections for the treatment of back pain

Treatment	Therapeutic and diagnostic injections for the treatment of back pain
Background	NHS Vale of York CCG is responsible for commissioning activity in secondary care, and this policy sets out the commissioning position and threshold for therapeutic and diagnostic injections for the treatment of back pain. This commissioning policy is needed because the clinical and cost effectiveness of therapeutic injections for back pain is not proven. There is a threshold in place for diagnostic injections for back pain prior to surgery and also for patients who are on an acute back pain pathway.
Commissioning position	NHS Vale of York CCG does NOT routinely commission **therapeutic spinal injections for back pain**. Therapeutic injections included in this policy are: • Epidural injections and nerve blocks • Facet joint injections (FJI) • Radiofrequency nerve denervation (rhizolysis/ medial branch block/ nerve root ablation) • Trigger point injections There are three exceptions (but note that ALL requests now have to be made via a referral form for prior approval) 1. For the treatment of **acute severe spinal pain or sciatica** of **up to 12 weeks duration**, as part of the acute/subacute back pain pathway, to help with mobilisation • one **epidural** or **transforaminal** injection will be commissioned within an acute back pain service 2. Facet joint injections for **diagnostic** purposes: Facet joint injections will NOT be commissioned for acute or acute on chronic spinal pain for **therapeutic** purposes For patient with complex multi level disease requiring **assessment for surgical intervention** (via specialist MSK service; orthopaedic or neurosurgical services) the CCG will commission a maximum of **two** facet joint injections for **diagnostic purposes** to help localise the problem and define surgical management of chronic spinal pain (which has lasted more than 2 years, with nerve root involvement). These should be performed no more than 6 weeks apart, as part of pre-surgical work up. 3. Spinal injections required to treat **cancer related spinal pain** (eg epidural or intrathecal injections, nerve blocks eg coeliac) – if other analgesia (oral, topical) has failed The CCG only considers spinal injections for patients with **chronic**

	spinal pain (>12 weeks) in clinically exceptional circumstances. **All patients with low back pain and/or sciatica should be assessed in line with NICE guidance NG59[1]. This MUST initially include** • Consider alternative diagnoses eg injury, malignancy • Risk assessment and risk stratification (eg STarT Back risk assessment tool at first point of contact with a healthcare processional). • Based on risk stratification, consider simpler support (eg self-management - exercise, weight loss etc) or more complex intensive support (eg pain management programmes (with physical and psychological elements), optimised pharmacological interventions All requests for **therapeutic** injections for chronic back pain, on the grounds of **clinical exceptionality**, need to be made to the NHS Vale of York CCG Individual Funding Request Panel process, using the Spinal Injection IFR form Approval is required by the NHS Vale of York CCG for both new patients, and patients for whom a repeat therapeutic back pain injection is being considered. General patient information is available at Back pain See also Sheffield back pain There is no shared decision-making guidance.
Summary of evidence / rationale	The new NICE clinical guideline on low back pain and sciatica in over 16s: assessment and management (NG59[1]) outlines the initial approach recommended. Assessment should include (especially if new or changed symptoms) considering alternative diagnoses (eg metastatic cord compression, spinal injury). For each new episode, risk assessment and stratification tools can help to clarify if less or more intensive support is required. Non-invasive treatments can include self-management, exercise, weight loss, manual or psychological therapy, combined programmes, and pharmacological interventions (RSS will cover in more detail) **Non-surgical invasive treatment[5]** 1. **Spinal injections (facet joint injections, FJI).** These involve injection of substances (local anaesthetic, steroid or other agents) into the facet joint itself. Facet joints are small stabilizing joints located between and behind adjacent vertebrae in the spine and are believed to contribute to spinal pain in some cases. Facet joint

injections can be used as a diagnostic procedure intended to establish whether the pain originates entirely or largely from the facet joint and may also be used as a therapeutic procedure for short-term pain relief.

Injection around the primary nerve innervating the facet joint (the medial branch of the posterior primary ramus) is termed a medial branch block. It can be used as a diagnostic procedure intended to establish whether pain originates from the facet joint, and it may also be used as a therapeutic procedure.

2. Radiofrequency denervation (RFD) (requires a positive response to a diagnostic medial branch block – ie FJI)

For people with low back pain who experience significant but short term relief with facet joint nerve blockade, this can be followed by a neurodestructive procedure called 'radiofrequency denervation' (RFD) in an attempt to achieve longer term pain relief. RFD has evolved as a treatment for spinal pain over the last 40 years and is a minimally invasive and percutaneous procedure. Radiofrequency energy is delivered along an insulated needle in contact with the target nerves and denatures them. This process may allow axons to regenerate with time requiring the repetition of the radiofrequency procedure. Radiofrequency denervation is not an appropriate treatment of people who have sciatica without back pain.

3. Epidurals/ nerve root injections

The epidural space lies within the spinal canal, outside the dura mater, and contains the spinal nerve roots. An epidural injection is an injection of a therapeutic substance into this canal, with the aim of a more regional response. This may be a caudal injection at the base of the spine, in the midline between the vertebral laminae (interlaminar epidural) or laterally, through the intervertebral foramen (transforaminal epidural, nerve root injection, dorsal root ganglion injection).

The most commonly used injection for the management of sciatica is corticosteroid, with or without local anaesthetic. Although performed widely since the 1950s, the administration of steroids into the epidural space remains unlicensed. Currently there are areas of uncertainty beyond the effectiveness of epidural injections to be considered, including the ideal route of administration, the use of imaging to improve accuracy, the timing of injection and the safety profile.

History of evidence base

The previous NICE clinical guideline on low back pain (CG88; May 2009) recommended that injection therapy should not be offered for back pain lasting greater than 6 weeks and less than 1 year[2]. It specifically states "Do not offer injections of therapeutic substances into the back for non-specific low back pain".

The NHS North Yorkshire Primary Care Trust established a policy in

line with this, reinforced by an evidence assessment published by YHEC in 2012[3]. In February 2014, the Centre for Reviews and Dissemination (University of York) carried out a rapid appraisal and summary of existing systematic reviews published since 2009[4]. This built on the fuller report from YHEC and concluded that current systematic reviews suggested there was insufficient evidence to support the use of injection therapy in patients with low back pain (or sciatica). The *do not do* recommendation by NICE remained appropriate.

This was part of a policy review considered by the CCG senior management team in 2014, where the policy was upheld, noting considerable expenditure on these injections and maintaining the system of request by clinical exceptionality only.

This was summarised at the time as "*The published evidence is inadequate to support the therapeutic use of facet joint injections, medial branch blocks or epidurals for chronic low back or neck pain. There is evidence from three published systematic reviews and one RCT that facet joint injections/medial branch blocks do not produce long term benefits in chronic back or neck pain in terms of employment status or pain. There are no published cost-effectiveness studies of facet joint injections*."

Recent activity

Activity data from 2015/16 and 2016/17 suggest that annual expenditure on FJI, RFD and epidurals for the VoY population has risen from around £125,000 to £175,000. For 2015/16, this comprises

- £70,000 for cervical, lumbar and sacral epidurals eg for spinal stenosis, sciatica (cost range £600-£1000; estimated about 115 procedures in 2016/17). (These are currently only funded for single treatments of acute back pain or for cancer pain - there is no mention of cancer-related treatment and only 6 recorded as IFRs.)
- £40,000 for facet joint injections eg for spondylosis, lumbar back pain (cost around £600; estimated around 112 procedures in 2016/17). (These are currently only funded for diagnostic purposes, as part of surgical assessment; only 6 recorded as IFRs).
- £10,000 for radiofrequency denervation (cost around £500; estimated around 25 procedures in 2016/17). (These are currently only funded through clinical exceptionality. It's not clear how these were approved; only 2 recorded as IFRs)

Further analysis of procedures carried out at York Hospital only during 2016/17 to end Dec 2016 shows that, of 102 procedures, 10 were associated with a cancer diagnosis. Ten of the remaining 92 were pairs of procedures about 6 months apart (total cost around £12,000) - 6 pairs of epidurals (cervical, thoracic, lumbar) and 4 pairs of facet joint injections. It is not clear how these fell within the criteria. Only 5

procedures overall were approved at IFR.

Current evidence base

The new NICE guidance NG59 maintains the current position not to offer spinal injections for managing low back pain and to consider epidurals only in people with acute and severe sciatica.

It does however include a new recommendation to "consider" referral for assessment for radiofrequency denervation (RFD) for people with chronic low back pain when:

- non-surgical treatment has not worked for them **and**
- the main source of pain is thought to come from structures supplied by the medial branch nerve **and**
- they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral.
- only to be performed in people with **chronic** low back pain (ie over 12 weeks) after a positive response to a diagnostic medial branch block.

The fuller NICE guideline (methods, evidence and recommendations) covers the evidence base in detail[5]. The quality of evidence is low to moderate in strength and comes from populations with chronic pain for more than 2 years who had failed to respond to conservative treatment[6]. It comments that the duration of pain relief following RFD is uncertain. Data from randomised controlled trials suggests relief is maintained for at least 6-12 months but no study has reported longer term outcomes. Some trials show adverse event (allodynia) rates higher than expected with RFD.

An original economic model was built for this guideline, based on pain scores reported in the clinical review conducted for the guideline and also on some expert opinion for duration of treatment effects. Assessment of pain, however, is inherently subjective and difficult to measure accurately – the placebo effect is often a significant factor, especially with injections, and other psychological factors have a major role in low back pain.

The model showed that RFD is "cost effective" but the results were sensitive to the duration of the intervention; it suggested that the treatment is likely to be cost effective **provided the duration of effect exceeds 16 months**. When this was less than 16 months, RFD was not cost effective as the ICER would go above the **£20,000 per QALY threshold**. This is, in itself, the upper limit of what is considered an acceptable threshold and takes no account of affordability. Given the relatively low cost of RFD (around £750 per procedure), it also suggests the impact is rather limited.

The guideline development group considered the various limitations of the model together with the main results and concluded that although RFD is a cost effective intervention, there was not enough confidence to make a strong ('offer') recommendation for this intervention. In

	addition, as the low back pain population is potentially very large, the group expressed concern about the potential cost impact of a strong recommendation. In addition, if RFD is repeated, there is no evidence to show whether the outcomes and duration of these outcomes are similar to the initial treatment. If repeated RFD is to be offered, more evidence is needed to be more certain that this intervention is both effective and cost effective. The CCG therefore propose to maintain the current commissioning position of only considering requests on the grounds of clinical exceptionality. This is in line with many other CCGs who have not made any change in commissioning position[6].
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References:

1. NICE NG59 (November 2016) Low back pain and sciatica in over 16s: assessment and management https://www.nice.org.uk/guidance/ng59
2. Low back pain: Early management of persistent non-specific low back pain NICE CG88 May 2009 http://publications.nice.org.uk/low-back-pain-cg88
3. Evidence Assessment: Therapeutic Spinal Injections For Chronic Back Pain York Health Economics Consortium June 2012
4. Evidence note - Spinal injections for the treatment of low back pain February 2014 Centre for Reviews and Dissemination (personal communication)
5. NG59 full guidance; invasive treatments: methods, evidence and recommendations https://www.nice.org.uk/guidance/ng59/evidence/full-guideline-invasive-treatments-2726157998
6. Bedfordshire and Hertfordshire interim priorities forum statement 55 (Nov 2016): Back injections: the elective use of epidural and facet joint injections and denervation of facet joints in management of back pain
7. Royal College of Surgeons - Commissioning guide: Low Back Pain: Broad Principles of the patient pathway (2013) "has been replaced by the NHS England guideline"
8. NHS Choices – Back Pain http://www.nhs.uk/Conditions/Back-pain/Pages/Introduction.aspx