NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

Interventional procedure HTG10168 (1790-2) Neurostimulation of lumbar multifidus for refractory chronic low back pain with lumbar multifidus dysfunction

Scope

1 Introduction

The procedure included in this NICE HealthTech evaluation is neurostimulation of lumbar multifidus for refractory chronic low back pain with lumbar multifidus dysfunction. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new and significantly modified procedures, or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This assessment is a review of existing NICE interventional procedures guidance on neurostimulation of lumbar muscles for refractory non-specific chronic low back pain. The methods and process for the assessment follow the Interventional procedures programme manual and the NICE HealthTech programme manual.

2 Summary of the procedure

Low back pain can be long term (chronic) and may not respond to treatment (refractory). Low back pain can happen when 1 of the muscles on either side

of the spine that support the lower back becomes weak or stops working properly (lumbar multifidus dysfunction).

In this procedure, a cut is made in the buttock or the outer side of the lower back and a small battery-powered device (a neurostimulator) is placed under the skin. A second small cut is made on the lower back and 2 electrical wires are inserted using a needle. The wires are placed near the nerves that control the muscles on either side of the spine. The wires are passed under the skin and connected to the neurostimulator, which sends low-voltage electricity that stimulates the nerves (neurostimulation). The procedure is done using general anaesthesia or local anaesthesia with sedation, and X-ray imaging to guide placement.

The person can use the device at home to stimulate the nerves, using a remote control. The aim is to stimulate the muscles in the lower back, help them work properly again, which may reduce pain, improve movement and function and quality of life.

3 The condition

Chronic low back pain is pain that lasts for 3 months or longer. If symptoms do not respond to medicines and non-invasive treatments the condition is called refractory. Some people with refractory chronic low back pain will have functional instability of the spine due to dysfunction of the lumbar multifidus (a large muscle that supports the spine). This can happen when pain causes muscles in the affected area to be less active as a reflex response. Over time the muscles then weaken, providing less protection and support to the spine. This can cause pain, stiffness, reduced function and fat infiltration of the multifidus (identified by MRI). The condition is caused by how the spine in the lower back moves and does not involve pain from the nerves.

4 Current practice

In the NHS, treatment for chronic low back pain follows NICE's guideline on low back pain and sciatica in over 16s. Initial treatment is delivered with a

focus on pain management and improving function. This includes medicines such as oral non-steroidal anti-inflammatory drugs, used at the lowest effective dose for shortest duration. These are used alongside non-invasive treatments including self-management advice and education, exercise, manual therapies, and psychological therapies. However, the NICE guideline does not provide specific guidance for people with refractory chronic low back pain with lumbar multifidus dysfunction.

5 Unmet need

There is no UK data for the prevalence of refractory chronic low back pain with lumbar multifidus dysfunction. However, it is estimated there are 5.5 million people in England (approximately 14% of adults) with chronic severe low back pain (Arthritis UK 2025).

There are a lack of treatment options for people with chronic low back pain with lumbar multifidus dysfunction. These people may experience disabling ongoing pain, reduced ability to carry out daily activities, and find it difficult to work (Lorio 2025). Neurostimulation of the lumbar multifidus muscles may offer a targeted treatment addressing this unmet need.

6 The procedure

The procedure is done as a day case under general anaesthesia, or local anaesthesia with sedation. A pulse generator (neurostimulator) is implanted in a pocket created under the skin of the upper buttock or lateral side of the lower back. Under fluoroscopic guidance an incision is made in the lower back and using a midline approach, 2 stimulating leads are inserted through an introducer needle. The distal end of each lead has 4 stimulation electrodes. They are positioned on either side of the spinal column, near the medial branch of the L2 motor nerve supply (dorsal ramus nerve) to the multifidus muscles, and fixed using flexible tines. The introducer needle is removed and leads are tunnelled internally under the skin to the pulse generator (neurostimulator), where the proximal ends are connected to the

neurostimulator. The position is checked using an X-ray and stimulation is tested to ensure correct placement.

Approximately 14 days after the procedure, the neurostimulator is configured and programmed by a healthcare professional to deliver stimulation between any pair of electrodes, allowing bilateral stimulation of the lumbar muscles as needed. The person can then start using the device. While lying prone, they use a handheld wireless remote control to deliver stimulation to the nerves of the lumbar multifidus muscles, which causes them to contract. This is usually done twice a day for about 30 minutes each time.

The aim of neurostimulation is to help the body restore neuromuscular control of the lumbar multifidus muscles by 'reactivating' them to help stabilise the spine, reducing muscle inhibition, improving pain, function and quality of life. The procedure is reversible.

6.1 Innovative aspects of the procedure

The proposed innovative aspect of the procedure is the neuromuscular mechanism of reactivating and controlling the lumbar multifidus muscles. Regular use of the device is intended to retrain the muscles, improve neuromuscular control and spinal stability over time.

6.2 Current known use of the procedure

The procedure is currently done in 21 NHS trusts in England. Barts Health NHS Trust, reported in 2025 doing approximately 100 implants since the procedure was introduced. A UK post-market clinical follow-up registry study in 5 NHS trusts reported that 42 people received this procedure between 2017 and 2018 (Leeds Teaching Hospitals, North Bristol, University Hospital Southampton, The Walton Centre Liverpool, and Mid and South Essex).

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

Chronic low back pain is more common among women than men affecting 54% of women compared to 49% of men (NHS Digital 2026). Factors such as multiple pregnancies are associated with increased risk of low back pain in women.

People from more deprived areas are more likely to have back pain (Yu 2023).

People from minority ethnic groups, may have problems accessing specialist services, because of barriers such as language, and cultural differences. As a result they may be less likely to receive this procedure.

Low back pain is the leading cause of disability in the UK (Arthritis UK 2025). People with refractory chronic low back pain with lumbar multifidus dysfunction may be covered by the Equality Act 2010 if their symptoms have a substantial adverse effect on day to day activities for longer than 12 months.

Some people with a physical disability, cognitive impairment or complex comorbidities may find it more difficult to undergo this procedure or to use a stimulation device.

This procedure is currently available in a limited number of specialist centres. This geographic variation may disadvantage people in areas without access to this treatment.

8 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of neurostimulation of lumbar multifidus for refractory chronic low back pain with

lumbar multifidus dysfunction to determine if it works well enough and is safe enough for use in the NHS.

Table 1: Decision problem

Population	Adults with refractory chronic low back pain with lumbar multifidus dysfunction
Intervention	Neurostimulation of lumbar multifidus following implantation of a neurostimulator
Key efficacy outcomes (may include but are not limited to)	• Successful implantation • Symptom relief (sustained pain relief) • Device explantation because of lack of efficacy • Device explantation because of pain resolution • Improvement in back function or stability (for example measured disability using Oswestry Disability Index) • Return to work • Activities of daily living • Quality of life • Reduced medication use • Satisfaction with the procedure

Key safety outcomes (may include but are not limited to)	• Procedure related adverse events
	• Device related adverse events
	  ○ Lead problems (migration, erosion, fracture)
	  ○ inadequate stimulation, intermittent stimulation, over stimulation, loss of stimulation
	• Wound complications (such as infection, haemorrhage, inflammation, hematoma near implantation site)
	• Post-operative surgical site pain
	• Discomfort from lead anchors or pocket
	• Muscle fatigue
	• Undesired sensations
	• Nerve irritation
	• Nerve damage or degeneration
	• Requirement for revision surgery
	• Device explantation because of adverse events

9 Other issues for information

According to the instructions for use, neurostimulation of the lumbar multifidus is indicated for use in ‘adults only for the management of mechanical chronic low back pain with multifidus muscle dysfunction, in people with moderate to severe pain and disability (lasting for more than 6 months) that has not responded to pain medications and physical therapy and are not candidates for spine surgery’. At present, one device ReActiv8 Restorative Neurostimulation system (Mainstay Medical Holdings Plc) is available for this indication.

The device may be affected by strong electromagnetic fields such as airport security systems. Some MRI scans may be restricted, but can be undertaken in certain conditions with manufacturer guidance and specialist advice.

10 NICE team

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Appendix A: Related evidence or guidance

Relevant registries

- British Spine Registry
- Spine Tango -EUROSPINE's International Spine Registry
- National neuromodulation Registry (NNR).

Emerging key trials

None

Related NICE guidance, standards or indicators

NICE HealthTech guidance

- Transaxial interbody lumbosacral fusion for severe chronic low back pain (2018) HealthTech guidance 478. (Recommendation: can be used).
- Peripheral nerve-field stimulation for chronic low back pain (2013) HealthTech guidance 309. (Recommendation: can be used during the evidence generation period).
- Deep brain stimulation for refractory chronic pain syndromes (excluding headache) (2011) HealthTech guidance 253. (Recommendation: can be used).
- Digital technologies for managing non-specific low back pain: early value assessment (2024) NICE Health technology evaluation. HTE16

NICE clinical guidelines

Low back pain and sciatica in over 16s: assessment and management (2016, updated 2020). NICE guideline 59

NICE technology appraisal guidance

VER-01 for treating chronic low back pain [ID6638] (In development)
Reference number: GID-TA11842 Expected publication date: TBC

NICE quality standards

Low back pain and sciatica in over 16s (2017), NICE quality standard 155 [QS155]

Other related documents

Non-NICE clinical guidelines

British Pain Society Neurostimulation guidelines March 2026 (in development)

International Society for the Advancement of Spine Surgery (ISASS) Position Consensus Statement 2025

Comprehensive Evidence-Based Guidelines for Implantable Peripheral Nerve Stimulation (PNS) in the Management of Chronic Pain: From the American Society Of Interventional Pain Physicians (ASIPP). 2024

Specialist interventions for managing chronic non-malignant pain in adults (2026) Scottish Health Technologies Group (SHTG). Healthcare Improvement Scotland.

An Evidence-Based Consensus for the Use of Neurostimulation for the Treatment of Non-Surgical Low Back Pain: The NEURON Group. American Society of Pain and Neuroscience (ASPN) 2025