NICE National Institute for Health and Care Excellence

NICE guidance

iFuse for treating chronic sacroiliac joint pain

Medical technologies guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 The case for adopting the iFuse implant system to treat chronic sacroiliac joint pain is supported by the evidence. Using iFuse leads to improved pain relief, better quality of life and less disability compared with non-surgical management.

1.2 iFuse should be considered for use in people with a confirmed diagnosis of chronic sacroiliac joint pain (based on clinical assessment and a positive response to a diagnostic injection of local anaesthetic in the sacroiliac joint) and whose pain is inadequately controlled by non-surgical management.

1.3 Cost modelling indicates that after 8 years, using iFuse instead of non-surgical management will save the NHS around £129 per patient. It is likely that savings will then increase over time. Savings mainly come from fewer steroid joint injections and less pain relief medication with iFuse compared with non-surgical management.

2 The technology

Description of the technology

2.1 The iFuse implant system (SI-Bone) is a titanium implant intended for use in people with chronic sacroiliac joint pain. iFuse is placed across the sacroiliac joint using minimally invasive surgery, where it is intended to stabilise the joint and to correct any misalignment or weakness that can cause chronic pain. The implant is triangular, which is designed to limit movement and spread shear stresses evenly. It has a porous metal coating, which the company claims promotes bone-on-bone growth and encourages joint fusion. Typically, 3 implants are used per joint, depending on the size of the pelvis. Implanting iFuse is a technically challenging procedure for which surgeons need specific training (provided at no additional cost by the company).

2.2 The cost of iFuse stated in the company's submission is £4,059, which includes 3 implants and the necessary consumables for the procedure. The cost of theatre time is estimated to be £1,310 per procedure (using HRG code HN13A-F – Major hip procedures from NHS reference costs for 2015/16).

2.3 The claimed benefits in the case for adoption presented by the company are listed in the scope of this evaluation.

Current management

2.4 Chronic sacroiliac joint pain can affect people of any age and usually needs lifelong management. The standard of care is escalating non-surgical management, typically beginning with analgesic therapy (such as non-steroidal anti-inflammatory drugs or opioids) combined with physiotherapy. If these initial treatments are ineffective, invasive procedures may be considered. These include steroid injections into the sacroiliac joint itself and radiofrequency ablation to the nerves that supply the joint. Sacroiliac joint fusion may be considered if the chronic pain continues. This can be done through open surgery or through a minimally invasive procedure, using a device such as iFuse. Invasive procedures and surgical treatments for chronic sacroiliac joint pain are usually done by spinal surgeons and orthopaedic trauma pelvic surgeons working in specialist centres.

2.5 NICE has published interventional procedures guidance on minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain, which may be done using iFuse. The guidance recommends that the evidence supporting the procedure is adequate for it to be carried out with standard arrangements for clinical governance, consent and audit. The guidance also recommends that the procedure should only be done in people with a confirmed diagnosis of unilateral or bilateral sacroiliac joint dysfunction due to degenerative sacroiliitis or sacroiliac joint disruption; and should only be carried out by surgeons who regularly use image-guided surgery for implant placement and have had specific training and expertise in minimally invasive sacroiliac joint fusion surgery for chronic pain.

2.6 The NICE guideline on low back pain and sciatica in over 16s refers to surgical interventions for treating low back pain and sciatica including spinal decompression, fusion and disc replacement. The guideline does not mention surgical interventions for treating sacroiliac joint pain.

3 Evidence

Summary of clinical evidence

3.1 The evidence for iFuse considered by the external assessment centre (EAC) came from 12 studies:

- 2 randomised controlled trials (n=251): Dengler et al. (2017b) and Polly et al. (2016a)
- 2 comparative studies
- 8 non-comparative studies.

Both randomised controlled trials compared iFuse with non-surgical management. In Dengler et al. (2017b), non-surgical management was analgesic therapy, physiotherapy and cognitive behavioural therapy; in Polly et al. (2016a), it was analgesic therapy, physiotherapy, steroid joint injections and radiofrequency ablation. Follow-up in the randomised controlled trials was relatively short (12 and 24 months), but in 1 comparative study, follow-up was 6 years after implanting iFuse. One study compared revision rates for iFuse with those for open surgery (Spain and Holt 2017). The company sponsored 9 of the 12 included studies, and in each sponsored study at least 1 author was a company employee. For full details of the clinical evidence, see section 2 of the assessment report.

EAC conclusions on the clinical evidence

3.2 The EAC concluded that the evidence shows that iFuse improves pain, improves health-related quality of life and reduces disability compared with non-surgical management. The EAC noted that the definition of non-surgical management differed between studies, but that it always included interventions that are representative of those used in the NHS for chronic sacroiliac joint pain. The EAC concluded that the evidence presented a reasonable estimate of the treatment effect of iFuse that was relevant to the population, intervention, comparators and outcomes detailed in the scope.

Summary of economic evidence

3.3 Neither the company nor the EAC identified any published economic evidence relevant to the decision problem. The company submitted 2 cost models,

1 comparing iFuse with open surgery and the other comparing iFuse with non-surgical management. Non-surgical management comprised a treatment pathway of analgesic medication, steroid joint injections and radiofrequency ablation. The assumptions and inputs of both models were based on clinical advice and UK pricing data, and both models used a 7-year time horizon. The EAC made some changes to the parameters and inputs of the company model. This included correcting errors and updating inputs and assumptions. For full details of the economic evidence and the EAC changes to the model, see section 3 of the assessment report.

EAC analysis of the economic evidence

3.4 In its assessment report, the EAC concluded that the model comparing iFuse with non-surgical management was most relevant to NHS practice. The revised model showed that after 7 years, iFuse was cost incurring by about £560 per patient because of the higher initial costs (including acquisition and procedure costs). The EAC also noted that as time passes, the costs associated with non-surgical management continue to be accrued, whereas for iFuse most of the costs are upfront. It judged this to be relevant to the cost consequences because lifelong management is normally needed for chronic sacroiliac joint pain and people are likely to have iFuse in place for the rest of their lives. The EAC therefore considered that cost savings with iFuse were plausible beyond the time horizon of the company's model.

3.5 The EAC extended the time horizon of the model to simulate the costs for lifelong management of chronic sacroiliac joint pain. The company also lowered the price of iFuse consumables at consultation stage from £275 to £136. Using this longer time horizon and lower consumable price, iFuse saves £129 per patient at 8 years, after which the savings continue to increase.

4 Committee discussion

Clinical effectiveness

4.1 The committee recognised the uncertainties in the published evidence but concluded that using iFuse to treat chronic sacroiliac pain is likely to lead to less pain, reduced disability and a better quality of life compared with non-surgical management.

4.2 The committee heard from a patient expert adviser who had complete pain relief soon after having iFuse implanted. They explained that iFuse had had a transformative effect on their life; after treatment, they were able to return to daily activities without being restricted by chronic pain. The clinical expert advisers confirmed that this accurately reflected the experience of their own patients who had iFuse implanted. The committee concluded that using iFuse could lead to considerable clinical benefits for people with chronic sacroiliac joint pain.

Comparator

4.3 The clinical expert advisers explained that people with sacroiliac joint pain are generally offered non-surgical management, with only a few centres offering sacroiliac joint fusion. When joint fusion is an option, minimally invasive techniques are usually preferred. The clinical expert advisers explained that open surgical sacroiliac joint fusion is not normally done because it is a technically challenging procedure that is associated with long recovery times, high revision rates and poor long-term results. The committee therefore concluded that non-surgical management was the most appropriate comparator in standard NHS practice against which iFuse should be assessed.

Impact of the disease

4.4 The clinical and patient expert advisers explained that chronic sacroiliac joint pain is an extremely debilitating condition that can restrict daily activities, affect mood and impair sleep. People with chronic sacroiliac joint pain are therefore likely to need strong analgesic medication that may include regular doses of opioids. People may also be offered steroid joint injections; the patient expert adviser explained that these injections are associated with a recovery period before discharge, such that they often involve taking time off work or away from

other responsibilities. The clinical expert advisers explained that steroid joint injections may be done every 6 months, but that the effects often last for only around 3 months. This can lead to some patients having a recurrence of chronic pain after a period of relief. They also noted that some commissioning bodies may not fund ongoing and repeated steroid injections. The committee also heard from the expert advisers that radiofrequency ablation is of limited therapeutic benefit. It concluded that chronic sacroiliac joint pain is generally managed with non-surgical treatments that are associated with potential side effects, patient inconvenience, and recurrent and inadequately controlled symptoms.

NHS considerations

Patient selection

4.5 The clinical expert advisers explained that chronic sacroiliac joint pain typically affects adults in middle age and that it is more common in women. Most patients are younger than 60 years, so face living with recurring symptoms over many years. The clinical expert advisers explained that chronic sacroiliac joint pain may result from inflammatory conditions affecting the joint, previous pelvic trauma (including from childbirth) and the transmitted shear stresses associated with previous spinal fusion. Some inflammatory conditions may resolve over time or with medication, so joint fusion procedures may not always be appropriate. The clinical expert advisers stated that they would not recommend using iFuse in people with osteoporosis in the bone adjacent to the sacroiliac joint, because this would increase the risk of device instability and incomplete joint fusion. However, they noted that once iFuse is implanted and the joint has fused, the risk of device and joint instability is low.

4.6 The clinical expert advisers explained the importance of an accurate diagnosis of chronic sacroiliac joint pain before iFuse is considered (that is, confirmation that the pain originates from sacroiliac joint dysfunction). The diagnosis needs to be confirmed by injecting local anaesthetic into the joint under image guidance. If the signs and symptoms are characteristic and the local anaesthetic joint injection provides pain relief, a diagnosis of chronic sacroiliac joint pain can be confirmed. MRI and CT scanning may also provide useful diagnostic information, particularly in people with multiple back issues.

4.7 The clinical expert advisers stated that sacroiliac joint pain is often misdiagnosed as pain originating from the lumbar spine or hip joint, and that sacroiliac joint dysfunction may sometimes not be considered as the cause for back pain. The patient expert adviser explained that this was reflective of their own experience. The committee concluded that sacroiliac joint pain is likely to be underdiagnosed, and an increased awareness of the condition among clinicians when assessing and treating low back pain would be beneficial.

Training of surgeons

4.8 Implanting iFuse is a technically challenging procedure during which there is a risk of damaging nerve roots and blood vessels adjacent to the sacroiliac joint. The company provides relevant and necessary training. The clinical expert advisers described the importance of taking part in training courses and in first doing the procedure under the supervision of a trained and experienced surgeon.

Cost savings

4.9 The committee noted that the company had submitted 2 models, 1 of which compared iFuse with open surgery. Having acknowledged that open surgical sacroiliac joint fusion is rarely done, the committee concluded that this model was not relevant to current NHS practice. It instead focused on the model that compared iFuse with non-surgical management.

4.10 The committee agreed with the changes the external assessment centre (EAC) had made to the company's cost model comparing iFuse with non-surgical management. The clinical expert advisers confirmed that the assumptions used in the cost models were representative of their experience with iFuse. For example, the model assumed that an overnight stay in hospital would usually be needed after having iFuse implanted, and that 3 (or occasionally 2 or 4) implants are used per joint treated. The expert advisers explained that single joint procedures are more common, but that some patients with bilateral disease may need a second procedure in the opposite joint months or years later. Around 60% of people have pain in both sacroiliac joints, but symptoms are usually more severe in 1 joint. The clinical expert advisers explained that standard practice would be to treat the joint with the most severe pain first, and then observe the treatment response before deciding on whether to use iFuse for the other joint.

Additional modelling by the EAC

4.11 The committee discussed the additional modelling by the EAC, which extended the time horizon to 30 years. The clinical expert advisers stated that most people with chronic sacroiliac joint pain will have repeated steroid joint injections (up to 3 a year) but that the injections will become less effective over time. They explained that it is unlikely anyone would have repeated steroid joint injections for up to 30 years because of the nature of the procedure and their reducing efficacy with time. After 30 years, people will have exhausted all other non-surgical management options and are likely to have to rely on analgesic medication alone. The committee noted that this was reflected in the longer 30-year time horizon implemented by the EAC, but the rate at which steroid injections decreased was based on informed opinion because no data were available.

4.12 The committee considered the longer time horizon to be appropriate and that it provided additional information, but recognised that it introduced uncertainty. Nonetheless, the experts predicted that the long-term performance of iFuse is likely to be good and that the risk of fracture or need for revision is low. They explained that any revisions are usually needed in the first few years after implantation; after this, the bone grows over the implant and across the sacroiliac joint, creating a permanent fusion that is stronger than the original joint and the surrounding bone. A company representative stated that the first iFuse devices were implanted in 2010 and that there are, to date, no reports of device failure after 2 years. The committee considered it plausible that iFuse may permanently relieve the symptoms of chronic sacroiliac joint pain. The committee concluded that after 8 years, using iFuse instead of non-surgical management could save around £129 per patient. It is likely after 8 years, these savings will increase over time to provide further value to the NHS.

5 Committee members and NICE project team

Committee members

This topic was considered by the medical technology advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal) and a technical adviser.

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Accreditation