

## THRESHOLD POLICY – T17 SPINAL SURGERY FOR ACUTE LUMBAR CONDITIONS

Policy author:	Ipswich and East Suffolk and West Suffolk CCGs with support from Public Health Suffolk
Policy start date:	September 2014
Subsequent reviews	February 2016
Next review date:	February 2020

### 1. Policy Summary

- 1.1 This policy covers chronic low back pain surgery and surgery for sciatica and spinal stenosis.
- 1.2 This policy does not apply to anyone <19 years of age.
- 1.3 Chronic low back pain is tension, soreness and/or stiffness in the lower back region<sup>1</sup> and which lasts more than 3 months/12 weeks<sup>2,3</sup>. The lower back is usually defined as the area from the bottom of the rib cage to the buttock crease although some people may also feel pain in their upper legs.
- 1.4 Sciatica is a symptom defined as unilateral, well-localised leg pain with a sharp, shooting or burning quality that approximates to the dermatomal distribution of the sciatic nerve down the posterior lateral aspect of the leg, and normally radiates to the foot or ankle
- 1.5 Spinal Stenosis is a condition that develops as a result of narrowing of the spinal canal leading to compression of the nerve roots. The vast majority of patients present with back and leg symptoms resulting in a reduced walking distance.
- 1.6 Spinal surgery for patients with chronic low back pain, sciatica and spinal stenosis is considered a low priority procedure and will not normally be funded except where patients meet the following criteria.
- 1.7 This policy will be reviewed in light of any updated NICE Clinical Guideline and when the National back pain pathway is published as part of the National Pathfinder project of NHS England.

### 2. Surgery for Chronic Low Back Pain: Eligibility and Background

#### 2.1 Eligibility Criteria

- a) Patients with chronic low back pain will be considered for surgical management under the following circumstances:
  - Spinal Fusion may be considered in selected patients with degenerative disc disease who are unresponsive to conservative therapy\* after one year and are being

documented as significantly interfering with quality of life (as measured by an appropriate measurement tool such as EuroQol5D)

- Patients should have a Body Mass Index of <30
- Patients should be non smoking\*\* at time of surgery as the rate of potential fusion is significantly affected by smoking.

\*Conservative management should include a combined physical and psychological treatment programme. Surgery will only be considered when there is documented evidence that the patient has engaged and has participated in the full programme.

\*\*Patients who smoke should have stopped smoking 8-12 weeks before surgery to reduce the risk of surgery and the risk of post-surgery complications and this should be determined by testing at an appropriate time during the pathway, for example at the pre-assessment clinic. The average waiting time for surgery is 12 weeks. Patients should be routinely offered referral to smoking cessation services to reduce these surgical risks.

## 2.2 Background to the Condition and Treatment

- a) It is estimated that up to 80% of population will seek help for spinal pain at some point in their lives. Whilst this is often a recurrent problem which can be managed in primary care, 5% develop persisting long term spinal pain, and a smaller percentage require specialist secondary care management for severe spinal pain<sup>4</sup>.
- b) Spinal fusion is a procedure that involves fusing together two or more vertebrae in the spine using bone grafts and spinal implants. Fusing of the spine is used primarily to eliminate pain caused by abnormal motion of the vertebrae<sup>5</sup>.

## 3. **Surgery for Sciatica & Spinal Stenosis: Eligibility and Background**

### 3.1 Eligibility Criteria

- a) Patients with sciatica and spinal stenosis will be considered for surgical management under the following circumstances:
  - A failure to improve over a 3 month period despite all the following conservative management where clinically appropriate:
    - (a) Physiotherapy
    - (b) Adequate analgesia including anti-neuropathic medication.

### 3.2 Exclusion Criteria

- a) Any patient presenting with abnormal or progressive neurology are excluded from this policy.

### 3.3 Background to the condition and Treatment

- a) Sciatica is a symptom defined as unilateral, well-localised leg pain with a sharp, shooting or burning quality that approximates to the dermatomal distribution of the sciatic nerve

down the posterior lateral aspect of the leg, and normally radiates to the foot or ankle. It is often associated with numbness or paraesthesia in the same distribution. The prevalence is in the region of 4-5%. Sciatica accounts for less than 5% of spinal conditions. Sciatica is as a result of a prolapsed intervertebral disc. Conservative management is the first line of treatment unless there is evidence of abnormal or progressive neurology. If symptoms fail to settle with conservative management, discectomy is a proven technique in carefully selected patients.

- b) Spinal Stenosis is a condition that develops as a result of narrowing of the spinal canal leading to compression of the nerve roots. This is a result of age related changes. The vast majority of patients present with back & leg symptoms resulting in a reduced walking distance. Conservative management is the first line of treatment. This includes a modification in lifestyle including exercise & weight loss. Regular analgesics including anti-neuropathic medication should be tried for a period of time. Surgery is indicated when conservative management has failed and in cases where there is abnormal or progressive neurological dysfunction.

#### 4. Rationale to the Decision

Evidence of Clinical Effectiveness:

##### 4.1 Spinal fusion

- a) Surgical site infection (SSI)<sup>10</sup> is a serious complication for spinal surgery. In a prospective cohort study of clinical data published in the Spine Journal, One thousand thirty (N=1,030) patients were included. All subjects underwent single level lumbar decompression, micro discectomy, or instrumented fusion. Results showed that the predisposing factors for SSI were **older age, higher BMI**, and the presence of certain comorbidities. The cumulative number of risk factors significantly associated with the increasing risk for an SSI ( $p < .0001$ ).
- b) One systematic review reviewed the efficacy of lumbar fusion surgery for chronic back pain treatment associated with lumbar disc degeneration (Mirza, 2007 from NICE CG88<sup>1</sup>) and the authors concluded that procedures may be more efficacious when compared to unstructured nonsurgical care but not so when compared to Cognitive behaviour therapy.
- c) A systematic review by Phillips<sup>2</sup> including 26 articles and a total of 3060 patients supported fusion surgery as a viable treatment option for reducing pain and improving function in patients with chronic low back pain, when a diagnosis of disc degeneration can be made. This was finding was based on six randomised studies which compared surgical versus non-surgical treatment in patients with moderately severe pain and disability lasting at least one year and who were unresponsive to standard nonsurgical therapy. These studies found a weighted average improvement in back pain of 35.3% (23%-47.6%) in the surgical group compared to 20% (9.2-30.8) in the non-surgical group.
- d) A systematic review of five high quality randomized controlled trials comparing surgery with conservative treatment for symptomatic lumbar spinal stenosis found that the implantation of a specific type of device or decompressive surgery, with or without fusion, is more effective than continued conservative treatment which had failed for 3 to 6 months<sup>6</sup>.

- e) NICE CG88 describes a meta-analysis of RCTs was conducted to compare surgical and non surgical treatment of lower back pain. This showed a benefit from surgery of 4.87 (95%CI: 1.62-8.12, P=0.003) as measured on the Oswestry disability index. (Ibrahim from NICE CG881)
- f) One systematic review concluded that “fusion surgery may be more effective than standard rehabilitation for improving pain at 2 years, but may be no more effective than intensive rehabilitation with a cognitive behavioural component for improving pain at 1 to 2 years in people with or without prior discectomy”<sup>3</sup>. This systematic review included four systematic reviews which compared surgery to non surgical treatment for chronic low back pain where a definitive diagnosis could not be made. All reported the same four high quality RCTs involving patients with non-specific back pain of at least 1 years duration where conservative treatment had failed and these RCTs displayed inconsistent results. One RCT found that fusion significantly improved pain and disability compared with non-surgical treatment at 2 years (VAS score 21.0 vs 4.2, p=0.002) and significantly increased proportion of people who returns to work (36% vs 15%, p=0.002). The three other RCTs compared surgery with intensive rehabilitation (incorporating CBT). The two smaller RCTs found no significant difference in pain and disability, whereas the other RCT found that fusion significantly improved ODI scores compared to non surgical treatment although this was not of ‘clinical importance’

#### 4.2 Discectomy

- a) One Cochrane review concluded that there was evidence that surgical discectomy provided effective clinical relief for carefully selected patients with sciatic due to lumbar disc prolapse that fails to resolve with conservative management. There was insufficient evidence however to ascertain the optimal timing of surgery<sup>7</sup>.
- b) A RCT of 283 patients who had severe sciatica for 6 to 12 weeks, compared early microdiscectomy with conservative treatment for six months followed by surgery for patients who did not show improvement. It found no significant difference in disability scores during the first year; however, relief of leg pain was faster for patients assigned to early surgery<sup>8</sup>.

#### 4.3 Laminectomy

- a) A systematic review by Jarrett<sup>9</sup> investigated the use of decompression surgery for spinal stenosis and concluded that decompressive surgery is more effective than land based exercise in the management of lumbar spinal stenosis, however it is a slowly progressive condition and conservative management should be considered first. This was based on 13 studies rated as moderate methodological quality using predominantly laminectomy as the type of decompression surgery. It stated that there was heterogeneity in the exercise interventions across the study and it was unable to state the most effective type of exercise programme.
- b) Evidence of cost effectiveness;

In terms of cost effectiveness a study examined surgical stabilisation (spinal fusion) vs. intensive rehabilitation for chronic back pain of at least one year’s duration in patients where the best treatment option was not known. It was found that there was a 20% probability that surgery would be cost effective at £30,000 per QALY. This probability

would increase if the least expensive surgery method was used and the differences between the groups were maintained for a further two years. The base case scenario was £48,588 per QALY (Rivero, 2005 from NICE CG88<sup>1</sup>).

c) Other NHS policies:

- A comparison of the clinical policies of various NHS commissioning organisations with respect to spinal surgery for chronic low back pain shows some variability across organizations, although surgery for chronic low back pain is nearly always a low priority procedure.
- In the absence of robust evidence from high quality research and considering the NHS policies elsewhere, Spinal fusion and discectomy for chronic low back pain should be considered as low priority procedure and is not routinely funded.

## 5. References

1. National Institute for Health and Clinical Excellence. Clinical Guideline (CG) 88 (2009) Early management of persistent non-specific low back pain
2. Phillips M, Slosar P, Youssef J, Andersson G, Papatheofanis F. Lumbar Spine Fusion for Chronic Low Back Pain Due to Degenerative Disc Disease. *SPINE*, Volume 38, Number 7, pp E409- E422. 2013
3. Chou R. Low back pain (chronic). *Clinical Evidence*, 2010, vol./is. 2010/, 1462-3846;1752-8526 (2010)
4. National Spinal Taskforce. Commissioning spinal services – getting the service back on track. A guide for commissioners of spinal services.
5. NHS Commissioning Board. Clinical Commissioning Policy Statement: Spinal Surgery for Chronic, Non-specific Low Back Pain. December 2012
6. Kovacs F, Urrutia G, Alarcon JD. Surgery versus Conservative Treatment for Symptomatic Lumbar Spinal Stenosis: A Systematic Review of Randomised Controlled Trials. *Spine*. 2011 36(20), E1335-1351
7. Gibson JNA, Waddell G. Surgical interventions for lumbar disc prolapse. *Cochrane Database of Systematic Reviews* 2007, Issue 2. Art. No.: CD001350. DOI: 10.1002/14651858.CD001350.pub4.
8. Peul W, van Houwelingen H, van den Hout W, Brand R, Eekhof J et al. Surgery versus Prolonged Conservative Treatment for Sciatica. *The New England Journal of Medicine* (2007); 356(22); 2245-56
9. Jarrett M, Orlando J, Grimmer-Somers K. The effectiveness of land based exercise compared to decompressive surgery in the management of lumbar spinal-canal stenosis: a systematic review. *BMC Musculoskeletal Disorders*. 2012, 13:30
10. Klemencsics I, Lazary A, Szoverfi Z, Bozsodi A, Eltes P, Varga PP. Risk factors for surgical site infection in elective routine degenerative lumbar surgeries. *The Spine Journal*. 2016 Aug 9, S1529-9430(16)30869-5. DOI: 10.1016