NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin090
Non-rigid stabilisation techniques for degenerative disease of the lumbar spine

Category 1 Intervention – Not routinely commissioned

Contents

Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 Where MCAS services are in place the patient needs to be seen in a Musculoskeletal Clinical Assessment (MCAS) service before referral to a consultant.

1.2 Non-rigid stabilisation techniques for degenerative disease of the lumbar spine are not routinely commissioned.

2. Exclusions

2.1 The focus of this policy is degenerative disease of the lumbar spine. Other indications are outside the scope of this policy.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 There is limited evidence to support the effectiveness and cost-effectiveness of these techniques in comparison with other operative techniques or conservative management.

5. Summary of evidence review and references

5.1 Guidance

NICE interventional procedure guidance (IPG) 366 was published in 2010[1] and stated that non-rigid stabilisation techniques are effective for a proportion of patients with intractable back pain resulting from degenerative change affecting the discs and facet joints. It identified no major safety concerns. The guidance recommended that they may be used with normal arrangements for clinical governance, consent and audit. The guidance was based on the evidence available at the time, which consisted of a small number of non-randomised comparative studies and case series. Where a comparator was available, studies primarily compared non-rigid stabilisation techniques to spinal fusion. There was no evidence comparing non-rigid stabilisation with conservative management. Included patients had degenerative lumbar disease, including spondylolisthesis, stenosis and herniated discs.

In 2016, NICE published Guidance NG59: "Low back pain and sciatica in over 16s: assessment and management"[2], which recommended that spinal fusion should only be performed in the context of a randomised control trial. The evidence review for this guidance was comprehensive in relation to anterior and posterior lumbar interbody fusion for low back pain caused by degenerative disease but excluded other fusion techniques and non-rigid stabilisation. It also excluded fusion for spondylolisthesis.

The National Low Back and Radicular Pain Pathway, published in 2017, states that flexible spinal stabilisation is 'discredited' but does not discuss the basis for this statement[3].

5.2 Research evidence

The primary indication for non-rigid stabilisation is as an alternative to spinal fusion for degenerative lumbar disease, often alongside decompression. Spinal fusion for low back pain is not commissioned on the basis of the recommendation made by NICE NG59[2]. This rapid review of the evidence aims to determine whether non-rigid stabilisation is superior to spinal fusion, other surgical procedures or conservative management for degenerative back pain.

This review only considers evidence published since the NICE IPG in 2010 and focuses on systematic reviews and randomised control trials (RCTs).

5.3 Non-rigid stabilisation for degenerative lumbar disease

Since 2010, there have been three systematic review and meta-analyses of the Dynesys non-rigid stabilisation system[4,5,6]. All have some issues with the methodological quality of the reviews themselves, as well as the relatively low quality of the included studies, which were almost all retrospective, non-randomised studies. Studies included patients with lumbar degenerative diseases, including disc herniation, lumbar spinal stenosis, and low-grade degenerative spondylolisthesis. The included studies found that compared to fusion, the Dynesys system may have better operative outcomes, including operation time and blood loss, but is not superior in respect of pain and function.

A 2020 meta-analysis of a variety of devices used as dynamic stabilisation adjacent to fusion found that dynamic stabilisation was superior to fusion alone in respect of one measure of adjacent segment disease, as well as finding a small positive effect for leg pain[7]. There was no significant difference in functional outcomes, operative outcomes or back pain after 3 months follow-up. The included studies were primarily retrospective, non-randomised studies and there was significant evidence of publication bias. This suggests that studies with positive findings are overrepresented.

A meta-analysis of the Coflex device for patients with lumbar spinal stenosis found better operative outcomes, including blood loss, operation time and length of hospital stay. Some improvements in pain and functional scores compared to fusion were seen in the short-term, but not at long-term follow-up[8]. These findings are supported by a 2017 meta-analysis of Coflex for a similar cohort, which did not identify any difference in function or device-related complications at long-term follow-up, though it did identify a marginal benefit for Coflex in pain scores[9].

Systematic reviews of a variety of dynamic stabilisation devices used for spinal stenosis, spondylosis, spondylolisthesis and degenerative disc disease have not identified a benefit for dynamic stabilisation compared to decompression alone or fusion in terms of pain or function.[10-12] Compared to fusion surgery dynamic stabilisation procedures were shorter, with less intra-operative blood loss, but reoperation rates were similar. Some included studies reported a higher complication rate for fusion.

A recent multi-centre RCT of dynamic pedicle-based stabilisation compared to fusion for degenerative lumbar disease found no difference in function, pain or quality of life scores at 2 years follow up.[13] There was also no difference in overall success rates. There was no difference between groups in secondary procedures or adverse events, but the absolute rate of adverse events and reoperations was high: out of 184 patients, 20 (10.8%) required reoperation. This reoperation rate is consistent with other studies.[14] Unfortunately, the study was underpowered and therefore unlikely to detect significant differences between groups. Two small RCTs comparing decompression with decompression plus use of the Wallis device in people with low back pain resulting from disc herniation found no difference in outcomes or adverse events.[15,16]

5.4 Non-rigid stabilisation for spondylolisthesis

Many of the studies above included patients with low grade spondylolisthesis, though most did not report results separately by indication. Two RCTs included only patients with low grade spondylolisthesis. One reported no benefit for decompression plus dynamic stabilisation compared to decompression plus fusion. It also compared both interventions to decompression alone, finding no benefit for dynamic stabilisation or fusion at 1 and 5 years follow-up, as well as longer operative time and increased operative blood loss.[17] The other RCT reported mixed results for a comparison of the TOPS system with transforaminal lumbar interbody fusion (TLIF).[18]

5.5 Cost-effectiveness

Several studies have suggested that dynamic stabilisation may be more cost-effective than fusion surgery, primarily due to the shorter operation time.[13,19,20] There is some evidence comparing the X-STOP device to decompression alone, which found that decompression alone was more cost-effective due to very high reoperation rates, as well as the device costs associated with X-STOP and the lack of improvement in outcomes.[21,22] In general however, the cost-effectiveness evidence comparing dynamic stabilisation to decompression alone or non-operative management is very limited.

5.6 Summary

The evidence base does not support commissioning non-rigid stabilisation techniques for degenerative disease of the lumbar spine. Dynamic stabilisation techniques are associated with shorter operation times and less intra-operative blood loss than spinal fusion surgery, which means they may be cost-effective in comparison to spinal fusion. The evidence also suggests a similar rate of adverse events. Dynamic stabilisation does not however result in better outcomes than spinal fusion. Almost all the studies cited in this review compared non-rigid stabilisation to fusion surgery, with few studies comparing it to decompression surgery alone or non-operative interventions. This is an important limitation of the evidence base, since fusion surgery itself lacks evidence of effectiveness for people with degenerative disease of the lumbar spine.

The studies that have compared non-rigid stabilisation to decompression alone have found no benefit from non-rigid stabilisation, alongside increased costs and harms.

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6. Advice and Guidance

6.1 **Aim and Objectives**

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms ‘men’ and ‘women’ are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 **Core Principles**

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.

- Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
- Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
- Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
- Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
- Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
- Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 Cosmetic Surgery

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

6.5 Diagnostic Procedures

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 **Clinical Trials**

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**
None

9.2 **International classification of diseases (ICD-10)**
None

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