Clinical Commissioning Policy: Bone morphogenetic protein-2 in spinal fusion

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Clinical Commissioning Policy: Bone morphogenetic protein-2 in spinal fusion

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Policy Statement

NHS England will commission bone morphogenetic protein-2 in spinal fusion in accordance with the criteria outlined in this document. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources. This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About the current treatment

Spinal fusion surgery can be used to treat back problems.

- The operation permanently joins together bones in the spine.
- This means that there is no movement between the bones.

The aim of a successful fusion is to allow the patient to move freely and with reduced pain.

One way of fusing the spine is by removing the intervertebral disc (one section of the spine) and replacing it with a solid cage. The cage supports the structure of the spine. It is filled with material which encourages the bones around the cage to fuse.

Usually bone from the patient's own body is used as this material (an ‘autologous graft’). The bone must be removed from somewhere else in the body at the time of the operation.

About the new treatment

Instead of using the patient’s own bone material, a material called ‘bone morphogenetic protein-2’ (rhBMP-2) may be used instead.

What we have decided

NHS England has carefully reviewed the evidence for using bone morphogenetic protein-2 in specialised spinal fusion surgeries. We have concluded that there is sufficient evidence consider making this treatment available for a selected group of patients who are more likely to benefit.

1 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission recombinant human bone morphogenetic protein-2 in spinal fusion surgery.

NHS England is responsible for commissioning complex spinal surgery as set out within the Manual for Prescribed Services (NHS England, November 2012). The commissioning criteria for complex spinal surgery which is commissioned by NHS England is documented within NHSE Policy D14/S/a.

Spinal fusion surgery permanently joins bones in the spine to ensure that there is no movement between them. The aim of a successful fusion is to reduce pain and disability. Fusions can be performed by removing the intervertebral disc and replacing it with a cage designed to maintain (or correct) the anatomical alignment of the lumbar spine. The cage is filled with material to encourage a fusion to occur.

The types of surgery covered by this policy: Anterior lumbar interbody fusion (primary and revision), posterior interbody fusion (primary and revision) of more than two levels, posterior lumbar instrumented fusion of more than two levels and posterior cervical or thoracic instrumented fusion with no spinal cord decompression.

A lumbar spinal fusion is performed: (a) when the pain is thought to be due to degenerative change at one or two levels in the lumbar spine, (b) to stabilise the spine following decompression of neurological structures where the decompression results in potential instability, (c) to correct and stabilise a spinal deformity which is usually performed at multiple levels and may require decompression of the neurological structures.

The use of autologous bone graft (ABG), typically an iliac crest bone graft (ICBG), as an adjunct to spinal fusion surgery is considered the gold standard. The use of bone graft possesses the three key properties required for bone formation: osteoconductivity (acts as a scaffold allowing native bone to perpetuate),

osteoinductivity (stimulates osteoprogenitor cells to differentiate into osteoblasts that then begin new bone formation), and osteogenicity (osteoblasts originating from the bone graft material contribute to new bone growth along with bone growth generated via the other two mechanisms). However, it may not be suitable for all patients, especially those who do not have sufficient quality iliac of crest bone material, where it has been harvested for previous surgery or where the bone is required for secure fixation as part of the spinal instrumentation.

Bone morphogenetic protein (BMP) is a graft substitute. Currently, the BMP with the widest clinical application is recombinant human bone morphogenetic protein-2 (rhBMP-2), an osteoinductive bone growth factor that is a member of the transforming growth factor-b superfamily.

2 Definitions

The spine curves are divided in to three areas: neck (cervical spine), upper and mid back (thoracic), and lower back (lumbar).

Pseudoarthrosis (or non-union) in the spine is where the bones show no chance of fusing without intervention.

Autologous (or autogenous) bone grafts involve utilising bone obtained from the same individual receiving the graft. Bone can be harvested from non-essential bones, such as the iliac crest (hip).

Recombinant human bone morphogenetic protein-2 (dibotermin alfa, rhBMP-2) is an osteoinductive protein which, when carried on an absorbable collagen sponge (matrix), can induce new bone growth at the site of implantation. It binds to receptors on the surface of mesenchymal cells and causes cells to differentiate into cartilage- and bone- forming cells. The differentiated cells form trabecular bone as the matrix is degraded, with vascular invasion evident at the same time. The bone formation process develops from the outside of the implant towards the centre until the entire implant is replaced by trabecular bone.

Lumbar fusion is a spinal fusion surgery specifically in the lower spine. Multilevel (across two or more levels of the spine) lumbar fusion is rare and will only be considered for patients with severe, disabling pain where all options have been considered.

Posterior and posterolateral fusion involves decortication of the bone at the back (posterior) aspect of the spine (laminae and transverse processes) and application of a material to aid or induce bone formation.

A posterior lumbar interbody fusion (PLIF) involves adding bone graft to an area of the spine to set up a biological response that causes the bone to grow between the two vertebral elements and thereby stop the motion at that segment. This requires highly specialised expertise where the fusion is across more than 2 vertebral elements.

Anterior lumbar interbody fusion (ALIF) is similar to posterior lumbar interbody fusion except that in ALIF the disc space is fused by approaching the spine through the abdomen instead of through the lower back. Anterior spinal fusion is a surgery performed by removing the intervertebral disc and replacing it with a cage, designed to maintain (or correct) the anatomical alignment of the spine, which is filled with a material to aid or induce bone formation. Due to the positioning of the patient during this surgery, the ability to harvest bone from the iliac crest is more limited in anterior spinal fusion.

Posterior cervical and thoracic fusion is the same as for the lumbar spine with decortication of the posterior elements (laminae) and application of a material to aid or induce bone formation.

3 Aims and Objectives

This policy proposition aims to define NHS England's commissioning position on rhBMP-2 as part of the treatment pathway for adults undergoing spinal fusion surgery where this is the responsibility of NHS England specialised commissioning teams.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults undergoing spinal fusion surgery.

4 Epidemiology and Needs Assessment

Low back pain is a common disorder, affecting around one third of the UK adult population each year. Approximately 1 in 15 of the population will consult their GP about the pain. Referral for surgery is usually only considered when non-surgical options have not been successful.

While the majority of complex spinal fusion surgery will be performed using an autologous graft, expert clinical opinion suggests that this may not be a viable option for some patients. For these patients, rhBMP-2 may be considered in the following indications in specialised spinal surgery:

1. ALIF (primary or revision): It is estimated that about 500 of these procedures are performed by the NHS in England each year. ICBG would be used in the majority of these procedures. Based on clinical opinion, rhBMP-2 could be used in around 30 patients each year.

2. PLIF or transforaminal lumbar interbody fusion (TLIF); more than 2 levels: It is impossible to accurately predict the number of patients receiving rhBMP-2 but expert clinical opinion would suggest this could be the case for up to 10 patients each year.

3. Posterior lumbar instrumented fusion (more than 2 levels): It is estimated that around 400 of these procedures are performed by the NHS England each year. However, most of these will use ICBG or other product. Based on clinical opinion, it is estimated that rhBMP-2 could be used in around 100 patients each year.

4. Posterior cervical or thoracic instrumented fusion: These would be very rare indications, requiring urgent surgical treatment to prevent long term disability and

morbidity. Again, it is impossible to accurately predict the number of patients but expert clinical opinion would suggest this could be the case for up to 10 patients each year.

This means approximately 150 patients per year may require rhBMP-2.

5 Evidence base

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of bone morphogenetic protein-2 for anterior lumbar interbody fusion surgery, posterior interbody fusion more than 2 levels, posterior lumbar instrumented fusion more than two levels, and posterior cervical and thoracic instrumented fusion with no spinal cord decompression only for patients who have failed fusion from previous iliac crest bone graft (ICBG) or where ICBG cannot be harvested.

The evidence review has sought to establish the clinical effectiveness, safety and cost effectiveness of rhBMP-2 in comparison with iliac crest bone graft for anterior lumber spinal fusion surgery and posterior instrumented spinal surgery to inform the NHS England policy.

Clinical effectiveness:

The evidence for clinical effectiveness of BMP is based on five good quality independent systematic reviews and meta-analyses (Chen et al., 2012; Fu et al., 2013; Simmonds et al., 2013; Zhang et al., 2014; Noshchenko et al., 2014). The number of studies included in the reviews varied depending on the inclusion and exclusion criteria but all included 8 RCTs evaluating rhBMP-2 with ICBG for lumbar fusion (including ALIF). All reviews compared rhBMP-2 with ICBG for spinal fusion and the primary outcomes were rate of fusion and improvement of clinical symptoms based on the ODI and the SF-36, physical scale. The quality of reporting secondary outcomes varied across studies.

Fu et al. (2013) and Simmonds et al. (2013) systematic reviews were conducted as part of The Yale University Open Data Access (YODA) Project. In addition to the published studies, individual-participant data was obtained from sponsors or investigators to address the issue of publication bias.

The results of the analysis on the primary outcome measure indicate that compared with ICBG, rhBMP-2 in lumbar fusion (single level anterior or posterior fusion) has higher rates of radiographic fusion at 2 years follow up period. The relative risk (RR) for radiographic fusion varied from 1.13 to 1.19, with 2 reviews showing a statistically significant difference.

Successful fusion was not, however, correlated with improvement in clinical outcomes as measured by: the Oswestry Disability Index (ODI), return to work, back pain, leg pain and SF-36. Both groups had improvements in clinical outcomes but at 2 years follow up there was no statistically significant difference between the two groups. Similar results were observed in a recently published RCT of 197 patients with a 4 years follow up (Hurlbert et al., 2013). After 4 years of follow up, radiographical fusion rates remained significantly higher in patients treated with rhBMP-2 (94%) than those who received autograft (69%) (p=0.007). However, SF-36, ODI and leg/back pain scores were comparable between the 2 groups.

The rate of non-union at two years postoperative was significantly lower in the rhBMP-2 groups (including off-label use) and was approximately half that of the ICBG groups. However, this did not lead to similar improvement for patient centred outcomes and funnel plot analysis indicated an asymmetry of published results, with a tendency to underestimate the non-union risk for rhBMP-2, this may be suggestive of a publication bias (Noshchenko et al., 2014).

Subgroup analysis by type of surgery: ALIF and PLF or PLIF found similar results for fusion rates and clinical outcomes (Fu et al., 2013).

Radiological fusion and patient related clinical outcomes:

As radiological fusion is used as the primary outcome measure, the clinical relevance of successful fusion after lumbar arthrodesis with rhBMP-2 or ICBG was studied in a meta-analysis by Noshchenko et al. (2015). This study concluded that patients who had radiological fusion had significantly better clinical outcome measures (ODI and Numeric Rating Scales (NRS) for back and leg pain) but fusion used on its own was a poor predictor of clinical outcomes, indicating that other factors contributed to patient related clinical outcome measures.

Overall, it can be concluded that successful fusion using rhBMP-2 is not strongly correlated with improvement in clinical outcomes and it should be noted that no trials were independent of industry sponsorship.

Safety:

The initial reports from industry sponsored trials reported low levels of side effects resulting from the use of rhBMP-2. However, a systematic review by Carragee et al. (2011) reported that adverse events associated with rhBMP-2 use in spine fusion ranged from 10% to 50% (depending on approach) in comparison to the 0% reported in some industry sponsored trials.

Adverse events for ALIF were not directly reported however anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events in the early postoperative period, including life-threatening events. PLIF use was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes. In posterolateral fusions the risk of adverse effects associated with rhBMP-2 use was equivalent to, or greater than, that of iliac crest bone graft harvesting and 15% to 20% of subjects reported early adverse events of back pain and leg pain. Higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy (Carragee et al., 2011).

Similar levels of side effects from rhBMP-2 have been reported in other reviews. A meta-analysis involving 184,324 patients (28,815 rhBMP-2 group, 155,509 ICBG

group) from 26 studies published between 2002-2013 by Vavken et al. (2015), reported significantly higher risk of general complications with rhBMP-2 compared to ICBG with an odds ratio (OR) of 1.78 (95% CI 1.20–2.63, p=0.004). The OR for heterotrophic ossification (HO) was 5.57 (95% CI 1.90–16.36, p=0.002), for retrograde ejaculation 3.31 (95% CI 1.20–9.09, p=0.020), and for cervical swelling 4.72 (95% CI 1.42–15.67, p=0.011), all significantly higher in the rhBMP-2 group. Other outcomes such as perioperative clinical outcomes including blood loss, complications/adverse events, and hospital stay were not significantly different between the rhBMP-2 and ICBG groups.

A recent study retrospectively analysed data from 460,773 patients who underwent lumbar spine fusion either without rhBMP-2 (69.3%) or with (30.7%) (Savage et al, 2015). A slightly lower complication rate was reported with rhBMP-2 group (18.2%) compared to the control group (18.7%) (RR 0.976, CI 0.963–0.989, p<0.001). In both treatment groups, patients older than 65 years had a significantly higher risk of postoperative complications than the younger patients (p<0.001). However in patients younger than 65 years, those treated with rhBMP-2 had higher rate of complications compared to control group (RR 1.042, CI 1.017–1.067, p<0.001), whereas in the patients ≥ 65 years old, the opposite was true i.e. lower complication rates in rhBMP-2 group (RR 0.950, CI 0.935–0.065). For both males and females, the complication rates were lower in the rhBMP-2 group than in the control group but it was only significantly lower in females, RR 0.974, CI 0.953–0.995, p=0.015 in males compared to RR 0.976, CI 0.960–0.993, p=0.005 in females. The authors also report 90-day reoperation rates of 1.84% in the control group, which was significantly lower compared to 2.03% in the rhBMP-2 group (RR 1.108, CI 1.060–1.158, p<0.01). In both the control and rhBMP-2 groups, patients younger than 65 years were more likely to have a reoperation than patients older than 65 years (p<0.001). In this study the difference in response (overall, age, and gender specific) for rhBMP-2 and non-rhBMP-2 patients cited by the authors has limited implication in a real world setting given the nearly 1 RR in all cases.

The outcomes that favoured rhBMP-2 compared to ICBG were mean operative time for patients, which was less for patients treated with rhBMP-2 than that of patients who underwent ICBG harvest, and the number of patients requiring additional

surgical treatment during two postoperative years, which was also significantly lower in the rhBMP-2 groups (Zhang et al., 2014).

Nearly 50% of the patients who underwent lumbar fusion with ICBG experienced donor site pain at two years follow up and the risk of complications at the ICBG donor site was 7% (Noshchenko et al., 2014).

Cost effectiveness:

The evidence of cost effectiveness is based on two studies, one systematic review of studies evaluating cost effectiveness of rhBMP-2 against ICBG (Hsu et al., 2014) and one cost utility analysis in 33 patients receiving posterior lumbar fusion using rhBMP-2 (Alvin et al., 2014).

The systematic review included 5 studies (Polly et al., 2003; Garrison et al., 2007; Alt et al., 2009; Carreon et al., 2009; AHRQ, 2010) that compared fusion with rhBMP-2 to fusion with ICBG in patients with degenerative disease of the lumbar spine. In all cases, two year time horizon was used and no discounting was performed. All relied on a single non inferiority randomised trial (Burkus et al., 2002) for clinical data that served as the pivotal trial for FDA approval of Infuse® (Medtronic Sofamor Danek Inc., Memphis, TN). Two studies (AHRQ, 2010; Garrison et al., 2007) relied solely on this RCT, one (Alt et al., 2009) also used data from two other non-randomised trials of the same grafts inserted laparoscopically, and one (Polly et al., 2003) also used expert opinion. Two studies (AHRQ, 2010; Garrison et al., 2007) undertook cost-utility analyses (CUA) from a payer perspective. Both derived utility estimates from unpublished preoperative and 6-month SF-36 data from the trial.

There were conflicting conclusions reached depending on the type of data used, cost-measurement methods and study design. For example, the Hsu et al. (2014) study used cost of treatment and hospitalisation data from the NHS study (Garrison et al. 2007) in the United Kingdom and concluded that rhBMP-2 was not cost-effective, rhBMP-2 versus ICBG was associated with £120,390 per QALY gained. No sensitivity analysis was performed.

Conversely, Alt et al. (2009) reported data including return-to-work parameters from 3 different European countries and concluded that the increased loss of productivity seen from the ICBG group resulted in a savings with use of rhBMP-2 per patient. Outcome measures used in the analysis included need for secondary surgery and return-to-work. Compared with ICBG, rhBMP-2 use resulted in savings ranging from £236 to £529 per patient as a result of decreased rates of secondary surgery and £4938 to £5450 savings from prevented lost productivity. The authors concluded that from a societal perspective, use of rhBMP-2 resulted in savings over time that offset the higher upfront cost of rhBMP-2 use compared with ICBG. All of the studies in the review had limitations including: lack of time horizon discounting, basis on a single RCT with a short time scale (two years), lack of sensitivity analysis (Alt et al., 2009; Carreon et al., 2009) and no inclusion of indirect costs in all except Alt et al. (2009). All studies except AHRQ (2010) and Garrison et al. (2007) were linked to sponsoring from manufacturers of rhBMP-2. In another study, Alvin et al. (2014) demonstrated that the one-year cost-utility ratio (Total Cost/ΔQALY) for the ICBG cohort was significantly lower (£94,177/QALY gained) than that of the rhBMP-2 cohort (£179,092/QALY gained) ($p<0.01$).

A cost effective analysis by Virk et al. (2012) suggested that while rhBMP-2 has better cost per QALY (£10,910/QALY) compared to ICBG (£14,008/QALY), the sensitivity analysis shows that rhBMP2 is not the most cost-effective option if the revision rate is raised. The findings from a recent population level study by Savage et al. (2015) showed that the 90 day reoperation rate in a group using rhBMP-2 for lumbar spinal fusion was higher than group using non-rhBMP-2 methods (RR 1.108, CI 1.060–1.158).

Based on the current evidence it can be concluded that there is no clear evidence that using rhBMP-2 is more cost effective than ICBG.

This clinical evidence review also considered the following specific questions related to the clinical effectiveness, safety and cost effectiveness of rhBMP-2.

Question 1: Is the use of rhBMP-2 safe and effective (in terms of clinical and radiographical outcomes) when used in adults for revision spinal fusion surgery when autologous bone graft (ABG) has previously been used and failed to achieve union (pseudoarthrosis)?

Evidence on the use of rhBMP-2 in revision spinal fusion surgery is available from one retrospective cohort study by Taghavi et al. (2010), however this considered posterior lumbar fusion only. The objective of this study was to determine the efficacy of rhBMP-2 or local bone, to either allograft combined with bone marrow aspirate (BMA) or autograft, in revision instrumented, posterolateral fusions (PLF). Indications for revision surgery included: symptomatic pseudoarthrosis (pain and/or instability) following a previous PLF for degenerative conditions of the lumbar spine, such as degenerative disc disease, stenosis, or spondylolisthesis. Sixty-two patients were divided into 3 groups: group 1 (n=24) received rhBMP-2, group 2 (n=8) received BMA/allograft, and group 3 (n=20) received autograft. The exact source of autograft bone for group 3 was not clearly defined. All three cohorts received supplemental local bone. Static and dynamic radiographs were used to assess fusion and clinical outcome was determined through Visual Analogue Scale (VAS) scores. At two years follow up, there was no difference between group 1 and 3, a fusion rate of 100% was observed for both groups. Similarly, no difference in VAS score was observed between group 1 and group 3.

The ability to generalise the results is limited due to the retrospective nature of the study design and sample size.

Dorward et al. (2013) evaluated cervical fusion rates with rhBMP-2 in 57 patients, this group included 48 patients (84.2%) who had undergone previous cervical surgery, and 42.1% who had a pre-existing non-union. Successful fusion was seen in 89.5% of patients. The neurologic symptoms were resolved postoperatively in 50 patients (87.7%) and both VAS and Neck Disability Index (NDI) scores improved significantly from baseline. The results were not provided in subgroups by previous surgery or non-union. The study is also limited by the lack of a comparator group, a lack of randomisation and sample size.

Question 2: Is the use of rhBMP-2 safe and effective (in terms of clinical and radiographical outcomes) when used in adults for primary spinal fusion surgery where there is high risk of pseudoarthrosis compared with ABG alone?

There are a limited number of studies evaluating the risk of pseudoarthrosis when using rhBMP-2 in people with one or more risk factors.

A study by Lee et al. (2013) compared fusion rates for rhBMP-2 versus autograft in patients with fusion-related risk factors. Fusion related high risk factors were defined as:
(i) old age (>65 years);
(ii) pseudoarthrosis with a T-score of less than -2.5 based on dual energy X-ray absorptiometry;
(iii) those who had continuously smoked for at least 1 year before surgery;
(iv) postoperative, medical comorbidities, including those who were receiving treatment for 2 or more concurrent medical diseases such as diabetes mellitus, hypertension, and thyroid disease;
(v) revision surgery including cases in which surgery was performed for pseudoarthrosis; or
(vi) multilevel fusion cases in which >2 levels were surgically treated.
One hundred and ninety-five patients were divided into 4 groups depending on fusion material and the presence/absence of fusion-related risk factors for non-union: group A was defined as rhBMP-2 used in the presence of high-risk factors (FRRF), group B was defined as rhBMP-2 used in the absence of FRRF, group C was defined as autograft used in the presence of FRRF and group D was defined as autograft used in the absence of FRRF.

Although time to fusion was faster in group A than in group C in all fusion-related risk factors (age, sex, revision, fusion level, smoking, DM, osteoporosis, and comorbidity), there was no difference between groups A and C at 2 years follow up. Similarly, fusion rate was higher in group A than in group C in other fusion related

risk factors, except revision surgery but there was no difference between groups A and C in all fusion-related risk factors.

There was no difference in results for subjects who were over 65 years of age or for smokers.

6 Criteria for Commissioning

rhBMP-2 will be routinely commissioned for the following procedures:
a. ALIF (primary and revision)
b. PLIF, TLIF (primary and revision) more than two levels
c. Posterior lumbar instrumented fusion more than two levels
d. Posterior cervical or thoracic instrumented fusion with no spinal cord decompression

Inclusion criteria:
rhBMP-2 can be considered by a spinal multi-disciplinary team only where the following conditions are met, with the decision to treat fully documented:
- ICBG harvest is not possible due to poor bone quality or other lack of graft; OR
- Harvesting ICBG would weaken fixation in the pelvis; OR
- ICBG has resulted in fusion failure.

Exclusion criteria:
rhBMP-2 cannot be considered for:
- Paediatric patients below 18 years old; OR
- Patients with malignancy or a high risk of developing malignancy; OR
- Anterior cervical spine surgery; OR
- Patients where there is evidence of infection.

7 Patient Pathway

Patients with indications deemed eligible for rhBMP-2, as an adjunct to their spinal procedure, would have their treatment managed by a specialised team with experience of lumbar fusion surgery.

Below is a detailed outline of the patient pathway.

Once a patient has been assessed by an orthopaedic consultant in either secondary or tertiary care:

a) Clinical or radiological diagnosis will be confirmed.

b) Information about the procedure, its aims, risks and follow-up protocol will be given to the patient. Information related to rhBMP-2 will also be provided.

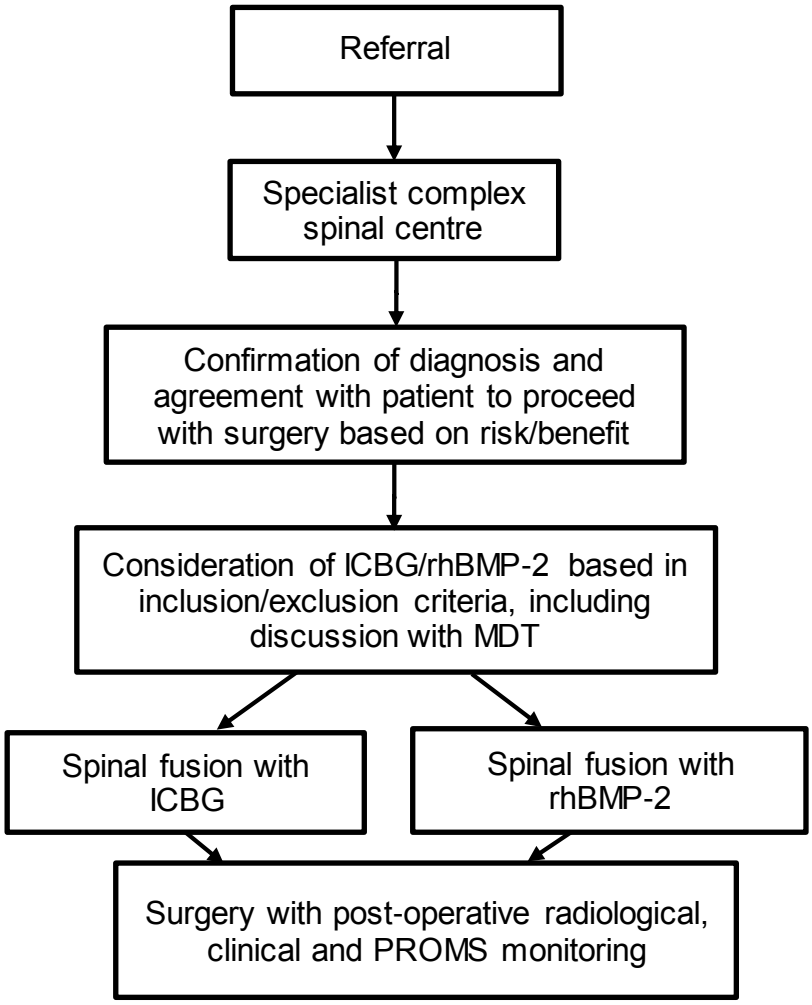
c) A decision will be made by a spinal multi-disciplinary Team (MDT) confirming the need for rhBMP-2 as part of the procedure following a discussion of other options. The site of application and spinal levels of surgery will be defined.

d) Surgery will be carried out by a specialist spinal surgeon with application of rhBMP-2 (reconstitution in accordance with the manufacturer's recommendations).

e) A British Spine Registry (BSR) form will be completed for monitoring purposes.

f) A radiograph must be performed at months 6, 12 and 24 to confirm that fusion has taken place successfully in the absence of complications. Clinical measures will also be recorded at these times in accordance with section 11 of this policy proposition.

All illustrative patient pathway is outlined below.



Dosage would be in line with manufacturer's guidance

8 Governance Arrangements

All spinal units performing procedures with rhBMP-2 must be recognised by NHS England as one of their listed designated centres for complex spinal surgery and specifically ALIF in accordance with the D14 Service Specification.

All centres must complete BSR documentation to receive the device exclusion payment equivalent to the cost of rhBMP-2.

9 Mechanism for Funding

Funding and commissioning of rhBMP-2 will be managed through the relevant local NHS England specialised commissioning team.

Reimbursement for rhBMP-2 is dependent on the completion of a British Spine Registry data form as outlined in section 11 of this policy proposition.

10 Audit Requirements

All patients who undergo spinal fusion surgery must complete a data form for the British Spine Registry (BSR) for monitoring purposes.

The following parameters should be collected at baseline and at months 6, 12 and 24:

- Fusion status (confirmed via radiograph)
- ODI (Oswestry disability index)
- VAS (10-point pain; visual analogue score)
- EQ-5D (quality of life)
- Complications
- Further surgery
- Re-admissions with spinal complications
- Return to theatre for spinal surgery

11 Documents which have informed this Policy

NHS Interim Clinical Commissioning Policy: Spinal Surgery. NHSE Policy N-SC/031. 2013.

NHS Standard contract for complex spinal surgery (all ages) NHSE Policy D14/S/a. 2013.

Greater Manchester EUR Policy Statement. Persistent non-specific low back pain. 2014.

12 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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