

Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	D14X01	D14X01	
Policy Title	Bone morphogenetic protein-2 in spina	al fusion	
Accountable Commissioner	David Stockdale	Clinical Lead	Ashley Cole
Finance Lead	Alison Taylor/Mandeep Dulku	Analytical Lead	Ceri Townley
	Section K - Activity Impact		
Theme	Questions	Comments (Include source made and any issues with	ce of information and details of assumptions the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	morphogenetic protein-2 (I surgery, for posterior instruinterbody fusion (more that thoracic instrumented spin patients who have failed fu (ICBG) or where ICBG care Back pain is a common co have low back pain in any persons in England in 201	s to routinely commission the use of bone BMP) for anterior lumbar interbody fusion umented lumbar fusion or posterior in two levels) and posterior cervical and isal surgery without decompression only for usion from previous iliac crest bone graft must be harvested. ¹ Indition: approximately a third of all adults given year, or an estimated c. 14.2m 4/15. ¹¹ Around 1 in 15 people will consult in This represents circa 3.6m adults in

K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	Specialised spinal surgery would only be performed on a small subset of those with back pain. K1.2 Under the proposed policy, only a small subset of those with back pain would be eligible for surgery using BMP. BMP would be used only for patients requiring surgery where ICBG was not feasible or had failed (please see the policy proposition for further detail). Currently, it is estimated that 150 patients might be suitable for BMP each year, split into three groups: • c. 30 patients per year for anterior lumbar interbody fusion (ALIF, primary or revision); • c. 10 patients per year for posterior interbody fusions (PLIF or TLIF); • c. 100 patients for posterior lumbar instrumented fusion; and • c. 10 patients per year who currently receive posterior cervical or thoracic instrumented fusion. In the first year of implementing the policy there could be a backlog of c. 70 patients. vi
K1.3 What age group is the treatment indicated for?	K1.3 The treatment is indicated for adults (of age 18 and above).vii
K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Use of BMP for spinal fusion surgeries may diminish in those of advanced age.viii

K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 The target population covered under the policy would be those patients undergoing specialised surgery where ICBG was not feasible or had failed.
	At present, the target population would be primarily undergoing specialised surgery as set out in K1.2:
	 c. 30 patients undergoing ALIF c. 10 patients undergoing PLIF or TLIF c. 100 patients undergoing posterior instrumented lumbar fusion c. 10 patients undergoing posterior cervical or thoracic instrumented fusion
	Of these patients, it is possible that BMP was used for c.135 per year.ix
	The remaining patients within the target population of 150 may currently be receiving alternative products for spinal fusion, including demineralised bone matrix, ceramics and hydroxyapatite. ^x
K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	K1.6 While various factors (see K2.2) may affect the prevalence of back pain, the effect of these cannot be quantified.xi As such, population growth would drive the projected growth of the condition: the number of persons with lower back pain could be estimate in the region of:xii
	 c. 14.4m in 2016/17 (year 1) c. 14.5m in 2017/18 (year 2) c. 14.8m in 2020/21 (year 5)
	The number who would visit their GP due to this pain could be in the region of: xiii
	c. 3.7m in 2016/17 (year 1)c. 3.7m in 2017/18 (year 2)

		• c. 3.8m in 2020/21 (year 5)
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2, 5 and 10 years?	K1.7 Under current policy, it assumed that activity set out in K1.5 would grow in line with demographic growth; as demographic growth is low, the number of patients having surgery with BMP or alternative products would remain at around 150 patients per year.
	K1.8 How is the population currently distributed geographically?	K1.8 Across England – no significant geographical differences have been identified.
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	K2.1 The new policy adds an additional treatment option for specialised spinal fusion surgery. Specifically, it refers to the use of bone morphogenetic protein-2 (BMP) for anterior lumbar interbody fusion surgery, for posterior instrumented lumbar fusion or posterior interbody fusion (more than two levels) and posterior cervical and thoracic instrumented spinal surgery without decompression only for patients who have failed fusion from previous iliac crest bone graft (ICBG) or where ICBG cannot be harvested.xiv
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	K2.2 Back pain may be associated with obesity, smoking, stress, or depression, and use of long-term medication which weaken bones (e.g. corticosteroids), as well as factors such as repetitive movement, slouching, and lifting.xv
		It has not been possible to quantify the effect of these factors on future growth.

	K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.	K2.3 None identified.
	K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 1, 2 and 5?	K2.4 Whilst it is estimated that currently ~135 patients may receive BMP for specialised spinal fusion surgery, under the policy the entire target population of approx. 150 patients per year could receive BMP, as identified in K1.2. Assuming 50% part year effect (PYE) in year 1 and 75% in year 2, the net increase in patients using BMP (as compared to the 'do nothing' scenario) could be estimated in the region of: xvi
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.	K3.1 The current activity for the target population is set out in question K1.5.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.	K3.2 Under the policy, the number of patients treated with BMP is estimated to be c.210 in year 1 (with a 50% phasing assumption, and including the backlog of c. 70 patients), c. 150 in year 2 (with 75% phasing), and c. 160 in subsequent years ^{xviii} It is estimated that there would be an equivalent decrease in the number of patients undergoing surgery with an alternative product . For patients in the target population, in future years, the use of alternative products would be close to nil.

	K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.	K3.3 If this policy is not adopted, then current activity, assumed to be the 'steady state' would be expected to roll forward in future years. The future activity levels are therefore estimated to be equal to those set out in K1.7.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	K4.1 The use of autologous bone graft, typically an iliac crest bone graft (ICBG), as an adjunct to spinal fusion surgery, is considered the gold standard.
	K4.2. What are the current treatment access criteria?	K4.2 Patients are considered for spinal fusion surgery if they still have severe low back pain despite having received optimal treatment as per NICE Lower Back Pain Pathway (G88).xix Specialised spinal surgical opinion would also need to support the use of spinal fusion surgery.
	K4.3 What are the current treatment stopping points?	K4.3 Not applicable as the intent of surgery is curative.
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.	K5.1 Alternative products for spinal fusion include demineralised bone matrix, ceramics and hydroxyapatite.*x

	K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K5.2 Not applicable as the intent of surgery is curative.
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.	K6.1 Once a patient has been assessed by an orthopaedic consultant in either secondary or tertiary care, the proposed pathway would be as follows: 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.
	K6.2 Where there are different stopping points on the pathway please indicate	K6.2 Not applicable as the intent of the surgery is curative.

	how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? Outpatient Mental Health Provider: Inpatient/Outpatient Community setting Homecare delivery	K7.1 BMP would be used in an inpatient setting as part of a surgical procedure.
	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? e.g. service capacity	K7.2 No change anticipated.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 BMP is a high cost drug excluded from tariff, so it should be captured in the high cost drug dataset for routine commissioning.xxi
	K8.2 How will this activity related to the	K8.2 Activity should be identified through the high cost drug dataset,

	new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	by drug name and indication. A standard naming convention is recommended.
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 No new or revised requirements anticipated.
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 It would be advisable that the patients that BMP should be followed up long-term using the British Spine Registry (BSR).
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 A BSR form will be completed for monitoring purposes. A radiograph must be performed at months 6, 12 and 24 to confirm that fusion has taken place successfully in the absence of complications.
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 Contract monitoring is required as BMP is an excluded drug and informing commissioners is a pre-requisite to receiving payment.
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5-K9.6 None identified.

	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. See also linked question in M1 below	K9.7 A software platform for prior approval would be used if available.
	Section L - Service	Impact
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 Service is currently organised through a network of accredited specialised spinal centres (see D14 Service Specification).xxii
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 No change anticipated.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 GPs, Physiotherapists, Pain management services, Orthopaedic and Spinal Consultants, tertiary centres.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No change anticipated.

	L2.3 Is the new policy likely to improve equity of access?	L2.3-2.4 New policy likely to improve equity and equality of access/outcomes for patients needing to undergo anterior lumbar surgery and posterior instrumented lumbar spine surgery due to the routine commissioning position for this group.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 Lead time required based on when rhBMP-2 supply becomes available again given current lack of supply due to manufacturing issues.
	L3.2 Is there a change in provider physical infrastructure required?	L3.2-3.7 No change anticipated.
	L3.3 Is there a change in provider staffing required?	
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	
	L3.5 Are there changes in the support services that need to be in place?	

	L3.6 Is there a change in provider / interprovider governance required? (e.g. ODN arrangements / prime contractor)	
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	L3.8 Publication and notification of new policy.
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	L4.1 No plans in the near future currently identified.
	Section M - Finance	Impact
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	M1.1 No, see M1.2.
	M1.2 Is this treatment excluded from	M1.2 Bone morphogenetic protein is a high cost drug excluded from tariff.xxiii

	national prices?	
	M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	M1.3 As an excluded drug, the price is subject to local negotiations. The list price is £2,023 (excl. VAT) for 1.5mg/ml of InductOs powder solvent, or £2,427.60 incl. VAT.xxiv For the cost of the drug per procedure, see M2.1.
	M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?	M1.4 Not applicable.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 The drug is administered in hospital. As such, VAT may not be recoverable.xxv VAT is included in the estimates in sections M2 and M3.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 No.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 Under the policy, the revenue cost per patient in year one comprises: i. the cost of BMP (which replaces an alternative product)
		ii. the cost of the procedure itself

		In specialised spinal fusion surgery, the cost of BMP per procedure is estimated to be c. £2,400 (including VAT).xxvi BMP could be used instead of alternatives (such as demineralised bone matrix, ceramics and hydroxyapatite).xxvii There would be an estimated savings of £400 to £700 per procedure as these products would not be used.xxviii The cost of the underlying procedure would vary little between operations with BMP or alternative products, and is estimated to be c. £8,200.xxiix
		Therefore the additional costs incurred per patient for BMP reflect the difference in product costs: c. £1,800 to £2,100 cost per patient based on the difference in cost between BMP and alternative products.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 In future years, no differences in the cost of the patient pathway were quantified.xxx
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.	M3.1 Cost pressure. There would be an estimated cost pressure to NHS England of c. £13k to £15k in year 1 (assuming 50% PYE and backlog effects), xxxi c. £20k to £23k in year 2 (75% PYE), and c. £27k to £32k in year 5 (FYE).xxxii
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured.	M3.2 Not applicable.

M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).	M4.1 This is expected to be cost neutral for other parts of the NHS.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.	M4.2 This is estimated to be a cost neutral (as set out in M3.1).
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured.	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 Not applicable.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. e.g. decommissioning less clinically or cost-effective services	M5.1 For consideration by CPAG.
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 No known material financial risks.

	M6.2 Can these be mitigated, if so how?	M6.2 No mitigations have been identified.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	M6.3 Although there may be long term and short term effects (such as revisions or consequences of treatment) that could impact the analysis, these are not quantified as the relative importance of each factor could not be estimated with confidence as some effects are long term.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? e.g. NICE appraisal, clinical trials or peer reviewed literature	M7.1 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, 2 year time horizon was used and no discounting was performed.
		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. If anything, the evidence suggests that the cost per QALY of rhBMP-2 is higher than ICBG.
	M7.2 What issues or risks are associated with this assessment? e.g. quality or availability of evidence	M7.2 All the studies in the systematic review relied on a single non inferiority randomized trial (Burkus et al., 2002) for clinical data that served as the pivotal trial for FDA approval of Medtronic Sofamor Danek Inc., (Memphis, TN) Infuse (rhBMP-2). The conclusions reached were based on low levels of evidence and study design, and

		industry sponsorship.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? e.g. Transitional costs, periodical costs	M8.1 None expected.
	M8.2 If so, confirm the source of funds to meet these costs.	M8.2 Not applicable.

ⁱ Policy proposition.

ii Based on rates noted in the policy proposition and applying these rates to 2014 ONS adult population data.

iii Policy proposition.

iv This uses an incidence rate of 1:15, and the population in England, based on ONS population data.

^v Please refer to the policy proposition.

vi As discussed with the policy working group, a backlog of c. six months of current activity (current activity is estimated at 135, see K1.5), could receive BMP in year 1.

vii The safety of BMP in children has not been established, http://www.medicines.org.uk/emc/medicine/26930, last accessed: 29/01/2016.

 $^{^{\}mbox{\tiny Viii}}$ Based on discussions with the policy working group.

ix Of the approx. 270 units of BMP reported as being used for spinal surgery by the manufacturer (based on 2012/13), an estimated c. 50% might be used for specialised interventions. Based on discussions with the policy working group.

^x Based on discussions with the policy working group.

xi Based on discussions with the policy working group.

The future figures were calculated based on the prevalence figures set out in K1.1 and assuming that growth is in line with population estimates, based on ONS population projections (2012) for the years 2014/15 to 2020/21.

- The future figures were calculated based on the prevalence figures set out in K1.1 and assuming that growth is in line with population estimates, based on ONS population projections (2012) for the years 2014/15 to 2020/21.
- xiv Policy proposition.
- xv NHS Choices, Back Pain Causes, accessed via: http://www.nhs.uk/Conditions/Back-pain/Pages/Causes.aspx, last accessed: 25/01/2016.
- xvi Figures are rounded to the nearest five.
- xvii It is estimated that the backlog of c. 70 patients (c. 6 months of the annual BMP estimate) would receive BMP under both the policy implementation scenario and the do nothing scenario, such that the backlog has no effect on net effects described in K2.4.
- xviii Please note that these figures are likely to increase with demographic growth over time, however given the low number of patients and low growth rate, this is expected to stay broadly constant within the five year period. Figures are rounded.
- xix NHS Standard Contract for Complex Spinal Surgery (all ages). (2013). https://www.england.nhs.uk/wp-content/uploads/2013/06/d14-comp-spinal-surg.pdf [Accessed 29/1/2016]
- xx Based on discussions with the policy working group.
- xxi See section K9 for further information.
- xxii NHS Standard Contract for Complex Spinal Surgery (all ages). (2013). https://www.england.nhs.uk/wp-content/uploads/2013/06/d14-comp-spinal-surg.pdf [Accessed 29/1/2016]
- xxiii NHS England Publications, 2014/15 National Tariff System, Annex 7B, High cost drugs and excluded devices.
- xxiv Dictionary of medicine, http://dmd.medicines.org.uk/DesktopDefault.aspx?AMP=8993011000001107&toc=nofloat, last accessed: 09/11/2015.
- xxv Section 3.2, When can goods being provided on prescription be zero-rated for VAT purposes? https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products. [Accessed 16/12/11].
- xxvi Figure rounded. Please refer to M1.3 for the base price estimate.
- xxvii Based on discussions with the policy working group.
- xxviii Figures estimates only, based on clinical consensus.
- xxix This is based on analysis of SUS data for OPCS codes in relation to fusion or instrumentation of spine; discussions with the policy working group.
- xxx There may be some differences in relation to revision rates, complications, and long term consequences of use. However, these are not quantified as the relative importance of each factor could not be estimated with confidence as some effects are long term.
- xxxi Please see K2.4 or K3.2 in relation to backlog assumptions.
- Full year effect. The ranges are driven by the cost of comparators, estimated at £700 in the low cost impact figures, and at £400 in the high cost impact figures, as compared to c. £2,500 for BMP. Figures based on the price differential between the treatment and the alternative for the additional patients using the treatment under the policy (as outlined in K2.4).