

**Integrated Impact Assessment Report for Clinical Commissioning Policies**

<b>Policy Reference Number</b>	B10X01		
<b>Policy Title</b>	Surgical correction for pectus deformity (all ages)		
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**Section K - Activity Impact**

<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	<p>K1.1 This policy proposes to <b>not routinely commission</b> surgical corrections of pectus deformities.</p> <p>The incidence of the pectus excavatum, the most common form of pectus deformity, is estimated at less than 10 per 1,000 population.<sup>i</sup> This relates to an estimated 546,000 people in England in 2014/15.<sup>ii</sup></p>
	K1.2 What is the number of patients currently eligible for the treatment under	<p>K1.2 Of the prevalent population, only those with relatively severe deformities would be recommended for surgery.<sup>iii</sup> The current number</p>

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the proposed policy?

of chest deformity operations carried out in England is estimated to be between 300 and 500 per year (between 0.06% to 0.09% of those with the condition).<sup>iv</sup>

K1.3 What age group is the treatment indicated for?

K1.3 This treatment is indicated for all ages.

K1.4 Describe the age distribution of the patient population taking up treatment?

K1.4 This treatment is typically taken up by younger patients. The majority of patients currently undergoing surgery are aged between 10 and 24.<sup>v</sup>

K1.5 What is the current activity associated with currently routinely commissioned care for this group?

K1.5 On average, around 400 procedures for correcting pectus deformities were carried out each year over the last 4.5 years, of which c. 210 each year related to patients aged under 18.<sup>vi</sup> An estimated 300 procedures related to correction of pectus deformity of the chest wall, an estimated 90 procedures per year were carried out in relation to prosthetic devices for the chest wall, and c. 10 per year for implants.<sup>vii</sup>

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 Pectus deformities are congenital, and in many cases would not lead to decreased survival.<sup>viii</sup> As such no increase in the incidence rate is expected. However, the number of patients with pectus deformities would grow in line with the overall population, and is estimated in the region of:<sup>ix</sup>

- ~ 554,000 in 2016/17
- ~ 558,000 in 2017/18
- ~ 569,000 in 2020/21

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	<p>K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years</p> <p>K1.8 How is the population currently distributed geographically?</p>	<p>K1.7 In the 'do nothing' case, the number of patients accessing the service is estimated to grow in line with the population. In future, it is estimated to be in the range of:<sup>x</sup></p> <ul style="list-style-type: none"> <li>• ~ 300 to 500 in 2016/17</li> <li>• ~ 300 to 500 in 2017/18</li> <li>• ~ 300 to 500 in 2020/21</li> </ul> <p>K1.8 Across England – no evidence of geographic variation in the population group was identified</p>
<p>K2 Future Patient Population &amp; Demography</p>	<p>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?</p> <p>K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)</p> <p>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</p>	<p>K2.1 The policy moves to a “non-routine commissioning” position.</p> <p>K2.2 The average age of patients undergoing pectus surgery has increased slightly in past years.<sup>xi</sup> Apart from this trend no factors were identified that might affect growth other than demographic factors.</p> <p>K2.3 None identified.</p>

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	<p>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 2, 5 and 10?</p>	<p>K2.4 Under the policy, there would be a decrease in the number of patients accessing the service. In 2016/17 there would be c. 150 to 250 fewer patients accessing the surgery. In future years there could be c.300 to 500 fewer patients accessing surgery.<sup>xii</sup></p> <p>The proposed policy establishes a ‘not routinely commissioned’ proposal for the relevant population (the specific cohort set out in K1.2). The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small.</p>
<p>K3 Activity</p>	<p>K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet</p> <p>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</p>	<p>K3.1 As set out in K1.2 and K1.5, current annual activity for correction of pectus deformity of chest wall was identified at between 300 and 500 procedures per year.</p> <p>K3.2 As the procedure is not routinely commissioned under the policy, it would not be undertaken by the NHS on a routine basis (as described in K2.4).</p> <p>It is also possible that there would be an increase in activity for comparator treatments such as subcutaneous implants or breast augmentation (described in K1.5); however, these are sub-optimal comparators and therefore the level of substitution towards such treatments is difficult to quantify.<sup>xiii</sup></p> <p>If patients do not take up the treatments listed above, they may receive no treatment under the NHS.<sup>xiv</sup></p>

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	<p>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</p>	<p>K3.3 Under a “do nothing” position, activity could remain similar to current projections as in K1.7 and in K3.1.</p>
<p>K4 Existing Patient Pathway</p>	<p>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</p> <p>K4.2. What are the current treatment access criteria?</p> <p>K4.3 What are the current treatment stopping points?</p>	<p>K4.1 Patients are referred to a specialist with pectus interest (thoracic, paediatric or units who offer joint practice). Treatment is determined by assessment of the type of pectus deformity, degree of deformity, simple vs mixed deformity, and determination of whether the deformity is isolated or part of a syndrome.</p> <p>Nuss and Ravitch are paid for by NHS England but are not specifically routinely commissioned. Bracing is not currently routinely commissioned. Other procedures such as implants are undertaken by plastic and not thoracic surgeons.</p> <p>K4.2 Assessment of psychological and physical impact of pectus deformity (i.e. baseline lung function) determine current treatment access. There is no consistent access criteria across the country.</p> <p>K4.3 Not applicable.</p>
<p>K5 Comparator (next best alternative treatment) Patient Pathway</p>	<p>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.</p>	<p>K5.1 Many patients may opt to do nothing if they can be reassured of the absence of any health concerns associated with the deformity.</p>

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	<p>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.</p>	<p>K5.2 Not applicable.</p>
<p>K6 New Patient Pathway</p>	<p>K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy</p> <p>K6.2 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.</p>	<p>K6.1 – K6.2 Not applicable as position is currently to not routinely commission.</p>
<p>K7 Treatment Setting</p>	<p>K7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> <li>○ Acute Trust: Inpatient/Daycase/</li> </ul>	<p>K7.1 Currently, the treatment is delivered in an inpatient setting.</p>

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	<p style="text-align: center;">Outpatient</p> <ul style="list-style-type: none"> <li>○ Mental Health Provider: Inpatient /Outpatient</li> <li>○ Community setting</li> <li>○ Homecare delivery</li> </ul> <p>K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p>	<p>K7.2 Estimated 3-6 month waiting list which would have to be honoured. As pectus surgery represents a small percentage (clinician estimate of c.2%) of surgical activity in the hospitals where it is carried out there is no appreciable impact on capacity or surgeon demand.</p>
K8 Coding	<p>K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>K8.1 The procedure for surgery would be recorded within SUS.</p> <p>K8.2 Not applicable as the position is to not routinely commission, however the OPCS code T021 would currently be applicable.</p>
K9 Monitoring	<p>K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? If so, these must be communicated to <a href="mailto:CTownley@nhs.net">CTownley@nhs.net</a>, ideally by end of October to inform following year's contract</p> <p>K9.2 If this treatment is a drug, what pharmacy monitoring is required?</p>	<p>K9.1 – K9.7 Not applicable.</p>

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	<p>K9.3 What analytical information /monitoring/ reporting is required?</p> <p>K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?</p> <p>K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</p> <p>K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. <i>See also linked question in M1 below</i></p>	
<b>Section L - Service Impact</b>		
<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (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	L1.1 Pectus surgery is currently offered in units with a specialist



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	<p>organised? (i.e. tertiary centres, networked provision)</p> <p>L1.2 How will the proposed policy change the way the commissioned service is organised?</p>	<p>interest (thoracic, paediatric or both).</p> <p>L1.2 Not applicable as the position is currently to not routinely commission.</p>
<p>L2 Geography &amp; Access</p>	<p>L2.1 Where do current referrals come from?</p> <p>L2.2 Will the new policy change / restrict / expand the sources of referral?</p> <p>L2.3 Is the new policy likely to improve equity of access</p> <p>L2.4 Is the new policy likely to improve equality of access / outcomes?</p>	<p>L2.1 Referrals mostly come from primary care but also from secondary surgical care.</p> <p>L2.2 The new policy will restrict the sources of referral as the procedure will no longer be available.</p> <p>L2.3 Equity will be improved by having a consistent commissioning position across England.</p> <p>L2.4 No.</p>
<p>L3 Implementation</p>	<p>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?</p> <p>L3.2 Is there a change in provider physical infrastructure required?</p>	<p>L3.1 There is currently a 3-6 month wait time for surgery (clinician estimate). However, as thoracic surgeons perform many of cancer surgeries that take priority over pectus surgery, the wait list in terms of absolute numbers of patients is not large.</p> <p>L3.2 No, the specialist equipment used for the Nuss procedure is very rarely kept on-site, instead being requested for the specific procedure.</p>

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	<p>L3.3 Is there a change in provider staffing required?</p> <p>L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p> <p>L3.5 Are there changes in the support services that need to be in place?</p> <p>L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>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)</p>	<p>L3.3-3.6 No, pectus surgery accounts for only a small percentage of surgical activity in the hospitals where it is performed so no changes to staffing or support services would be required.</p> <p>L3.7 Decrease as it will no longer be commissioned.</p> <p>L3.8 Not applicable.</p>
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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
<b>Section M - Finance Impact</b>		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	<p>M1.1 Is this treatment paid under a national prices*, and if so which?</p> <p>M1.2 Is this treatment excluded from national prices</p> <p>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?</p> <p>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</p> <p>M1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p>	<p>M1.1 Currently, pectus surgeries are paid under national tariff.<sup>xv</sup></p> <p>M1.2 No</p> <p>M1.3 No</p> <p>M1.4 Not applicable.</p> <p>M1.5 Not applicable.</p>



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	<p>M3.2 Where this has not been identified, set out the reasons why this cannot be measured</p>	<p>true comparators and would be difficult to quantify.</p> <p>M3.2 Not applicable</p>
<p>M4 Overall cost impact of this policy to the NHS as a whole</p>	<p>M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)</p> <p>M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole</p> <p>M4.3 Where this has not been identified, set out the reasons why this cannot be measured</p> <p>M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p>	<p>M4.1 Pectus surgery would currently fall under specialised services commissioned by NHS England.<sup>xx</sup></p> <p>It has been noted that pectus deformities can result in significant psychological problems for patients in teenage years.<sup>xxi</sup> Patients may therefore have increased need for other NHS services (such as mental health). However, there was not sufficient evidence found within the review to quantify the impact on mental health services by excluding pectus surgery from routine commissioning.</p> <p>M4.2 Cost saving. There is estimated to be a decrease in the total number of surgeries undertaken under the NHS (as described in M3.1).</p> <p>M4.3 Not applicable.</p> <p>M4.4 None identified.</p>

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M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified <i>e.g. decommissioning less clinically or cost-effective services</i>	M5.1 Not applicable.
M6 Financial Risks Associated with Implementing this Policy	<p>M6.1 What are the material financial risks to implementing this policy?</p> <p>M6.2 Can these be mitigated, if so how?</p> <p>M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>	<p>M6.1 There is some risk around the number of patients that would take up (suboptimal) comparator treatments as described in K3.2.</p> <p>M6.2 None identified.</p> <p>M6.3 Not applicable.</p>
M7 Value for Money	<p>M7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>M7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p>	<p>M7.1 No information collected regarding cost effectiveness of treatment as part of the evidence review.</p> <p>M7.2 Not applicable given lack of evidence identified.</p>
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i>	M8.1 None identified.

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	M8.2 If so, confirm the source of funds to meet these costs	M8.2 Not applicable.
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<sup>i</sup> Wheeler, K. Foote (2000). "Pectus excavatum: studiously ignored in the United Kingdom?", Archives of Disease in Childhood. 82(3). [Online] Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1718262/pdf/v082p00187.pdf> [Accessed: 19/11/2015]

<sup>ii</sup> This estimate applies the stated incidence rates to the population of England in 2014/15 obtained from the Office of National Statistics (ONS).

<sup>iii</sup> Based on discussions with the policy working group.

<sup>iv</sup> These figures are based on an extract of Secondary Uses Services (SUS) data and clinical discussions. The average procedures for the procedure code T021 (correction of pectus deformity) were around 300 per year over the period 2011/12 to 2015/16 (2015/16 data only to September 2015). Historically, there may have been up to an estimated 500 procedures per year (clinician estimates). For the adult population, the number of procedures may be declining year on year based on Ireland and Great Britain data in The Thoracic Surgery Registry, Brief Report for the Audit Years 2011-12 to 2013-14. SUS is the Secondary Uses Service data set used to record patient data in secondary health care. The unit of activity is a hospital spell.

<sup>v</sup> Based on Hospital Episodes Statistics (HES) 2013-2014. For the procedure code T021.

<sup>vi</sup> Based on a data extract from the Secondary Uses Service (SUS) data for the years 2011/12-2015/16 (2015/16 data only to September 2015) for patients with the ICD-10 codes Q676 (pectus excavatum), Q677 (pectus carinatum) or Q678 (other congenital deformities of chest) in one of the first three diagnostic positions of the spell.

<sup>vii</sup> These numbers assume that there is currently no unmet demand for the proposed procedures and hence those patients currently not receiving treatment will not be considered under the policy. Figures based on a SUS data extract from 2011/12 to 2015/16 as set out in footnote vi.

<sup>viii</sup> Although in severe cases there could be physiological morbidities as well as psychological impacts. Please see the policy proposition.

<sup>ix</sup> These numbers use the ONS English population projections from 2014/15 to 2020/21, multiplied by the prevalence rates set out in K1.1. The growth rate is applied to the prevalence rates reported in K1.1. Note that while a grading of evidence is applied to on the clinical evidence reviewed, the same level of assessment has not been applied to epidemiology figures.

<sup>x</sup> Figures estimated by applying the projected growth rate to the target population of 300-500 described in K1.2. Because patients may be more likely to undergo treatment for the condition while they are children and young adults (based on Hospital Episodes Statistics (HES) 2013-2014), Yearly forecast population growth figures (based on 2012 Census ONS population forecast) for the children and young adult population (ages 10 to 24) were applied to estimate the figures noted above. The average yearly growth rate for this cohort is 0% p.a. (compounded annual growth rate based on ONS population projections from 2015 to 2020).

<sup>xi</sup> Based on a comparison of HES data for the years 2009/10 and 2013/14 based on primary procedures for the OPCS code T021. In 2009/10 c. 16% of patients were aged between 0 and 14 years. This number decreased to 12% in 2013/15. Please also refer to the policy proposition.

<sup>xii</sup> This assumes that the policy will have full effect in 2017/18 and that 50% of activity would still remain in the system in 2016/17 (based on discussions with the policy working group).

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<sup>xiii</sup> Based on discussions with the policy working group.

<sup>xiv</sup> Based on discussions with the policy working group.

<sup>xv</sup> This procedure could fall under the HRG for thoracic procedures as identified in the 2013/14 HRG grouper.

<sup>xvi</sup> Estimate based on costed SUS data over the years 2011/12-2014/15 (for the procedure code T021). The review found no reason to believe that the cost would change if the policy is not implemented.

<sup>xvii</sup> Based on an initial attendance and a pre-assessment appointment with a thoracic surgery specialist (£277 and £146 based on 2014/15 tariff), an anaesthetics specialist (£125) and a follow up appointment with a thoracic surgery specialist (£146). A 10% Market Forces Factors (MFF) uplift is applied to these figures. Source: Great Ormond Street Hospital for Children. *Nuss Procedure*. [Online] Available from: <http://www.gosh.nhs.uk/medical-information/procedures-and-treatments/nuss-procedure> [Accessed: 19/11/2015].

<sup>xviii</sup> The costs noted here are an average cost that accounts for the specialised top up in cases where it would apply.

<sup>xix</sup> Based on 300 (or up to 500) surgeries undertaken at a cost of £3,700. Assumes that the policy has 50% effect in 2016/17 and 100% effect by 2017/18.

<sup>xx</sup> Based on NHS England Service Specification (E02/S/a). Paediatric Surgery: Surgery (and Surgical Pathology, Anaesthesia & Pain); and NHS England Manual for Prescribed Specialised Services 2013/14 [‘18. Adult thoracic surgery services’].

<sup>xxi</sup> No costs were identified, however clinicians note that there may be psychological costs to patients that are not able to access pectus correction surgery.