NHS
Cheshire and Merseyside

Clinical Commissioning Policy

Pectus Deformity, surgical treatment

Category 1 Intervention - Not routinely commissioned -

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Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
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1. Introduction

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

1.2 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 in Appendix 1.

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

2. Purpose

2.1 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.

3. Policy statement

3.1 Surgery for pectus deformity is not routinely commissioned.

4. Exclusions

4.1 None

5. Rationale

5.1 After conducting an extensive literature review, NHS England found that published evidence was insufficient to make conclusions to justify regular commissioning of surgery for pectus deformity.

5.2 This “not routinely commissioned” approach is consistent with neighbouring commissioners for a procedure which is widely considered to be cosmetic for the vast majority of patients.

6. Underpinning evidence

6.1 Pectus anomaly is a deformity of the sternum (breastbone) and commonly presents as 2 main types: *pectus excavatum* (“funnel” or “sunken” chest) and *pectus carinatum* (“pigeon chest”). Pectus excavatum (more common) is where the sternum is sunken inwards and the chest, therefore, looks hollow. In contrast, pectus carinatum (less common) is where the sternum is raised, and the chest is pushed out. Reported prevalence of pectus excavatum ranges from 6.28 – 12 cases per 1, 000 population around the world. In the UK, this has been reported as 7.9 cases per 1, 000.[1] It commonly affects 5 times more males than females[2] and is the most common chest wall deformity in children.[3]

6.2 Affected patients may have decreased lung volumes, evidence of lower airway obstruction and exercise intolerance, which is a common symptom associated with pectus excavatum, although this could be due to cardiovascular rather than pulmonary causes. Patients may also suffer psychological effects which may be disproportionately higher than the extent of the physical deformity.[4] A recent systematic review identified up to 20 genetic disorders which are associated with pectus excavatum and these included Ehlers-Danlos syndrome, Marfan's syndrome, neurofibromatosis, Noonan syndrome and Turner syndrome.[5]

6.3 The deformity arises as a result of variable degrees of posteriorly depressed sternal and cartilage attachments. The internally displaced chest wall may compress the heart and lungs which may result in exercise intolerance. Surgical repair is possible but the effectiveness of the procedure has been questioned.[6] One of the most common techniques is the Nuss procedure, first performed in 1987.[7] This is regarded as a minimally invasive technique where several small incisions are made on each side of the chest and a curved steel bar is then inserted between the ribs and sternum which pushes the sternum out and thus correcting the deformity.[8]

6.4 As far back as 2006, the effectiveness of surgical repair of pectus excavatum has been questioned. However, a systematic review and meta-analysis concluded that surgical repair significantly improves cardiovascular function and thus contradicting the argument that the procedure was primarily cosmetic without yielding any physiological improvement.[9] These findings were subsequently disputed on the grounds of a flawed analysis due to a high level of heterogeneity in the outcomes and inappropriate methods in most of the publications.[10] It has been suggested that one of the methodological problems in designing this type of research is there are currently no standard methods for assessing cardiovascular and pulmonary responses in this population. Making comparisons across studies is difficult if not impossible.[11] Anatomically, severity is identified using the Haller index[3] which is a series of CT scan measurements of the width and height of the chest wall, a value greater than 3.2 is deemed severe.[2] Another potential confounder, perhaps, is there is no direct correlation between the deformity appearance and the resultant clinical symptoms.[12]

6.5 A 2014 Cochrane review evaluated the effectiveness and safety of conventional surgery (Ravitch technique) compared with minimally invasive surgery (Nuss technique) for treating people with pectus excavatum. No RCTs were located and so the authors were unable to draw a conclusion as to the best surgical option for this condition.[1] Some authors have asserted that repair is indicated for decreased cardiopulmonary capacity rather than for cosmetic reasons and the procedure should be carried out after the paediatric growth spurt.[2]

6.6 Adverse effects, in a series of 1,034 patients from one centre treated using the Nuss technique over 10 years from 2008 – 2018, were reported as infection (1.4%) allergy to nickel (10.2%) and haemothorax (0.097%).[13] However, a recent systematic review studied the impact of the Nuss bars on the internal mammary artery flow. The results showed that internal mammary artery flow is compromised in 44% – 58% of patients with the bar in situ. Ten days after removal of the bar, some reversal of arterial flow was evident although in up to 67% of these patients, abnormal flow remained. The authors concluded further studies are required to determine whether this abnormal flow persists.[14] In addition, it has also been reported that following the Nuss procedure, post operative scoliosis is a rare condition but this can be resolved by the removal of the metallic bar.[15] Finally, there is a single case report of sudden cardiac arrest in a previously healthy 19 years old male who had undergone the Ravitch (open) procedure for severe pectus excavatum.[16]

6.7 There is little (if any) national guidance on the management of pectus deformity. In 2009, NICE issued interventional procedures guidance on the placement of the pectus bar for pectus excavatum. [8] IPG 310 considers the evidence on safety and efficacy is adequate to support its use provided that normal arrangements are in place for clinical governance and audit. "Normal" in this context requires the procedure to be carried out only by surgeons with cardiac and thoracic training and experience who are capable of managing cardiac or liver injury and where there are facilities for this. IPG 310 goes on to say the procedure should be carried out only by surgeons with specific training in inserting this device and the initial procedure should be performed with an experienced mentor.

6.8 In conclusion, this rapid review has shown that pectus anomaly (comprising mainly pectus excavatum) is extremely common especially in boys. Apart from the psychological impact of the cosmetic changes, there may be cardiopulmonary sequelae in some individuals. Of the 2 surgical repair methods, the Nuss technique is more common and less invasive. However, because there are no standard methods for assessing cardiovascular/pulmonary response in the affected population and also because the severity (as measured by physical appearance) doesn't seem to be linked to physiological outcomes, making comparisons across the literature is difficult. There are some concerns about the adverse effects associated with surgery and it is not surprising that NICE regard this procedure should only be undertaken in specialist units.

6.9 NHS England, in its policy[1] on surgery for pectus deformity, have specified that they will not routinely commission surgery for this condition. This policy was developed after an extensive literature review whose wide-ranging objectives included examining the impact of surgery on cardiovascular and psychological outcomes, relating severity to the degree of distress experienced and whether there was evidence for eligibility criteria and thresholds for surgery. Overall, NHS England found that the evidence was insufficient to make conclusions to justify regular commissioning.

6.10 Of the neighbouring CCGs, both North Staffordshire and Mersey CCGs have a not routinely commissioned policy whereas greater Manchester and Shropshire have no policy.

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7. Force

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.

8. Coding

8.1 **Office of Population Censuses and Surveys (OPCS)**
Any in the primary position
T02.1 Correction of pectus deformity of chest wall
T02.2 Insertion of silicone implant for correction of pectus excavatum
T02.3 Insertion of prosthesis into chest wall NEC

8.2 **International classification of diseases (ICD-10)**
With or without Q676 Pectus excavatum

9. Monitoring And Review

9.1 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

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

10. Quality and Equality Analysis

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

Appendix 1 - Core Objectives and Principles

Objectives

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.

Principles

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.

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.

Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

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 wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

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

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.

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.

Clinical Exceptionality

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.