NHS
Leeds
Clinical Commissioning Group

Aesthetic Breast Procedures Policy

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Name & Title of originator/author(s):	Dr Simon Stockill Medical Director, NHS Leeds CCG Dr Fiona Day, Consultant in Public Health Medicine, Leeds City Council
Name of responsible committee/individual:	Dr Simon Stockill, Medical Director, NHS Leeds CCG
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Executive Summary

This policy applies to all Individual Funding Requests (IFR) for people registered with General Practitioners in NHS Leeds CCG where the CCG is the responsible commissioner for this treatment or service. :

This policy does not apply where NHS Leeds CCG is not the responsible commissioner.

The policy updates all previous policies and must (where appropriate) be read in association with the other relevant NHS Leeds CCG commissioning policies, including but not limited to policies on cosmetic exceptions and non-commissioned activity.

All IFR and associated policies will be publically available on NHS Leeds CCG website

This policy relates specifically to:

Aesthetic Breast Surgery (including post weight loss, mastopexy, augmentation, revision of augmentation and implant removal, reduction, gynaecomastia, inverted nipples)

Contents

The Clinical Commissioning Groups (CCGs) (NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG) were established on 1 April 2013 under the Health and Social Care Act 2012 as the statutory bodies responsible for commissioning services for the patients for whom they are responsible in accordance with s3 National Health Service Act 2006. As at 1 April 2018 these three CCGs have merged to become NHS Leeds Clinical Commissioning Group

As part of these duties, there is a need to commission services which are evidence based, cost effective, improve health outcomes, reduce health inequalities and represent value for money for the taxpayer. NHS Leeds CCG is accountable to their constituent populations and Member Practices for funding decisions.

In relation to decisions on Individual Funding Requests (IFR), NHS Leeds CCG has a clear and transparent process and policy for decision making. They have a clear CCG specific appeals process to allow patients and their clinicians to be reassured that due process has been followed in IFR decisions made by the Non Commissioned Activity Panel, Cosmetic Exclusions and Exceptions Panel, or Non NICE Non Tariff Drug Panel (the IFR panels).

Due consideration must be given to IFRs for services or treatments which do not form part of core commissioning arrangements, or need to be assessed as exceptions to Leeds CCG Commissioning Policies. This process must be equitably applied to all IFRs.

All IFR and associated policies will be publically available on the internet for the CCG. Specialist services that are commissioned by NHS England or Public Health England are not included in this policy.

2 Purpose

The purpose of the IFR policy is to enable officers of NHS Leeds CCG to exercise their responsibilities properly and transparently in relation to IFRs, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions in relation to IFRs are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCG.

The policy outlines the process for decision making with regard to services/treatments which are not normally commissioned by the CCG in Leeds, and is designed to ensure consistency in this decision making process.

The policy is underpinned by the following key principles:

- The decisions of the IFR panels outlined in the policy are fair, reasonable and lawful, and are open to external scrutiny.

- Funding decisions are based on clinical evidence and not solely on the budgetary constraints.
- Compliance with standing financial instructions / and statutory instruments in the commissioning of healthcare in relation to contractual arrangements with providers.

Whilst the majority of service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the National Health Service (NHS). This may be due to advances in medicine or the introduction of new treatments and therapies or a new cross-Leeds Clinical Commissioning Group statement. The IFR process therefore provides a mechanism to allow drugs/treatments that are not routinely commissioned by the NHS Leeds CCG to be considered for individuals in exceptional circumstances.

3 Scope

Policy development and review: consultation and engagement

The policy was developed to:

- ensure a clear and transparent approach is in place for exceptional/individual funding request decision making; and
- provide reassurance to patients and clinicians that decisions are made in a fair, open, equitable and consistent manner.

It was originally developed in line with NICE or equivalent guidance where this was available or based on a review of scientific literature. This included engagement with hospital clinicians, general practice, CCG patient advisory groups, and the general public cascaded through a range, mechanisms.

The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy

NHS Leeds has established the processes outlined in this policy to consider and manage IFRs in relation to the following types of requests:

Aesthetic Breast Surgery (including post weight loss, mastopexy, augmentation, revision of augmentation and implant removal, reduction, gynaecomastia, inverted nipples)

NHS Leeds CCG *does not routinely commission* aesthetic (cosmetic) surgery and other related procedures that are medically unnecessary.

Providing certain criteria are met, the CCG will commission aesthetic (cosmetic) surgery and other procedures to improve the functioning of a body part or where medically necessary even if the surgery or procedure also improves or changes the appearance of a portion of the body.

Please note that, whilst this policy addresses many common procedures, it does not address all procedures that might be considered to be cosmetic. The CCG reserve the right not to commission other procedures considered cosmetic and not medically necessary. This policy is to be used in conjunction with the Individual Funding Requests (IFR) Policy for NHS Leeds CCG and other related policies.

NHS Leeds CCG routinely commission interventional procedures where National Institute for Health and Care Excellence (NICE) guidance arrangements indicate “normal” or “offered routinely” or “recommended as option(s)” and the evidence of safety and effectiveness is sufficiently robust.

NHS Leeds CCG *do not* routinely commission interventional procedures where NICE guidance arrangement indicates “special”, “other”, “research only” and “do not use”.

The commissioning statements for individual procedures are the same as those issued by NICE. (www.nice.org.uk).

An individual funding request (IFR) may be submitted for a patient who is felt to be an exception to the commissioning statements as per the Individual Funding Request Policy.

The CCG accept there are clinical situations that are unique (five or fewer patients) where an IFR is appropriate and exceptionality may be difficult to demonstrate.

Whilst the CCG is always interested in innovation that makes more effective use of resources, in year introduction of a procedure does not mean the CCG will routinely commission the use of the procedure.

An individual funding request is not an appropriate mechanism to introduce a new treatment for a group or cohort of patients. Where treatment is for a cohort larger than five patients, that is a proposal to develop the service, the introduction of a new procedure should go through the usual business planning process. CCG will not fund interventional procedures for cohorts over 5 patients introduced outside a business planning process.

Endpoints

Following completion of the agreed treatment, a proportionate follow up process will lead to a final review appointment with the clinician where both patient and clinician agree that a satisfactory end point has been reached. This should be at the discretion of the individual clinician and based on agreeing reasonable and acceptable clinical and/ or cosmetic outcomes.

Once the satisfactory end point has been agreed and achieved, the patient will be discharged from the service.

Requests for treatment for unacceptable outcomes post treatment will only be considered through the Individual Funding Request route. Such requests will only be considered where a) the patient was satisfied with the outcome at the time of discharge and b) becomes dissatisfied at a later date. In these circumstances the patient is not automatically entitled to further treatment. Any further treatment will therefore be the Clinical Commissioning Group's discretion, and will be considered on an exceptional basis in accordance with the IFR policy.

NHS Leeds CCG are committed to supporting patients to stop smoking in line with NICE guidance in order to improve short and long term patient outcomes and reduce health inequalities. Referring GPs and secondary care clinicians are reminded to ensure the patient is supported to stop smoking at every step along the elective pathway and especially for flap based procedures (in line with plastic surgery literature: abdominoplasty, panniculectomy, breast reduction, other breast procedures).

4 Definitions

The CCG is not prescriptive in their definitions. Each IFR will be considered on its merits, applying this Policy.

Routinely commissioned – this means that this intervention is routinely commissioned as outlined in the relevant policy, or when a particular threshold is met. Prior approval may or may not be required, refer to the policy for more information.

Exceptionality request – this means that for a service which is not routinely commissioned, or a threshold is not met, the clinician may request funding on the 'grounds of exceptionality' through the individual funding request process. Decisions on exceptionality will be made using the framework defined in the overarching policy 'Individual Funding Requests (IFR) Policy for the Clinical Commissioning Group in Leeds'.

5 Duties

The CCG will delegate its decision making in relation to IFRs to a delegated decision maker/s in accordance with its own scheme of delegation.

A delegated decision maker will attend the relevant IFR panel and will also have responsibility for approving the triage process. The triage process is the process of screening requests to see whether the request meets the policy criteria and which referrals need to be considered by an IFR panel; see sections on IFR panels for more information. This will be detailed in the CCG Scheme of Delegation

6 Main Body of Policy

Exceptionality funding can be applied for in line with the overarching policy through the IFR process if you believe your patient is an exception to the commissioning position. Please refer to the overarching policy for more information.

6.1 Cosmetic Breast Procedures for males and females Following Significant Weight Loss

Status: not routinely commissioned, prior approval via IFR process only

This framework applies for all patients who achieve significant weight loss either through weight management programmes or through Bariatric Surgery.

Removal of redundant skin folds resulting from weight loss after surgery or planned weight loss is not routinely commissioned by Leeds CCGs unless the criteria outlined below are met.

Primary eligibility criteria (for any of the above procedures)

- Patient's BMI must be 30 or less for 12 months AND
- There must have been at least 25% weight loss AND
- a period of more than 2 years must have elapsed since the weight loss surgery or period of significant weight loss AND
- Photographic evidence of the condition is required by the IFR panel – only photographs taken by medical photography will be accepted

Requests that do not meet these criteria will be rejected prior to panel unless there are very clear grounds for exception.

Leeds CCGs consider breast surgery in males or females following significant weight loss medically necessary where, in addition to the primary eligibility criteria listed above:

- There is persistent and recurrent skin breakdown or ulceration which the GP has been treating for 3 months or more OR
- Intertrigo which is resistant to at least 6 months of medical treatment

6.2 Breast Implant Removal and Reinsertion

Status: routinely commissioned in specific circumstances else prior approval via IFR process only

Leeds CCGs consider the removal of breast implants medically necessary for the following situations:

In patients who have undergone cosmetic augmentation mammoplasty or breast reconstruction following a medically necessary mastectomy (e.g. mastectomy for breast cancer or a prophylactic mastectomy), removal of

breast implants is considered medically necessary for any of the following indications:

- Remnant breast cancer or cancer in the contralateral breast, or
- Implants complicated by recurrent infections, or
- Implants with Baker Class IV contracture associated with severe pain, or
- Implants with severe contracture that interferes with mammography, or
- Intra- or extra-capsular rupture of silicone gel-filled implants.

The Baker classification is shown below.
For patients whose breast reconstruction followed a medically necessary mastectomy (i.e., mastectomy for breast cancer or a prophylactic mastectomy), breast implant removal is also considered medically necessary for these additional indications

- Baker Class III contracture, or
- Extra-capsular rupture of saline implant if the rupture compromises the cosmetic outcome of the implant.

Removal of ruptured saline-filled breast implants is not considered medically necessary for patients who have previously undergone cosmetic breast augmentation mammoplasty.

Requests for the removal of breast implants for any of the following indications is subject to a case by case review of the exceptional circumstances:

- Breast malposition or asymmetry; or
- Baker Class II contracture; or
- Baker Class III contracture that does not follow a medically necessary mastectomy; or
- Removal of breast implant due to patient's anxiety about developing an autoimmune disease; or
- Implant removal for biopsy of breast mass that has not been proven to be cancerous; or
- Implant removal for a mastectomy or lumpectomy that cannot be performed with the implant in place.
- Silicone Implant Removal for Autoimmune Disease
- Leeds CCGs do not consider either of the following medically necessary:
- Removal of silicone implants for autoimmune disease unless the patient meets at least one of the selection criteria listed above (e.g., rupture of silicone-gel filled implant, etc.); or
- IgG testing in connection with silicone implants (the development of IgG antibodies is neither specific to silicone implants nor indicative of autoimmune disorders).
- Reinsertion of Breast Implants

Although Leeds CCGs consider the removal of breast implants medically necessary for medical indications even if the implants were originally inserted for cosmetic purposes, the CCGs normally consider the reinsertion of new

breast implants to be cosmetic, and also consider mastopexy or adjustment surgery following implant removal cosmetic and hence will not be funded.

However, Leeds CCGs consider the insertion of replacement of breast implants following previous mastectomy (i.e., mastectomy for breast cancer or a prophylactic mastectomy) or for women with other significant developmental abnormalities (including Poland's syndrome) medically necessary.

Baker Classification:

Class I	Augmented breast feels soft as a normal breast.
Class II	Augmented breast is less soft and implant can be palpated, but is not visible.
Class III	Augmented breast is firm, palpable and the implant (or distortion) is visible
Class IV	Augmented breast is hard, painful, cold, tender, and distorted

6.3 Breast Augmentation or Reconstructive Surgery

Status: routinely commissioned for trauma or following breast cancer (to reconstruct the breast, correct for significant deformity, and to correct asymmetry); all other cases by prior approval via IFR process only

Leeds CCGs consider reconstructive breast surgery medically necessary after a mastectomy or lumpectomy that result in a significant deformity (i.e., mastectomy or lumpectomy for treatment of or prophylaxis for breast cancer and mastectomy or lumpectomy performed for chronic, severe fibrocystic breast disease, also known as cystic mastitis, unresponsive to medical therapy). Procedures include mastopexy, insertion of breast prostheses, the use of tissue expanders, or reconstruction with a transverse rectus abdominis myocutaneous (TRAM) flap, deep inferior epigastric perforator (DIEP) flap, or similar procedure. Leeds CCGs also consider associated nipple and areolar reconstruction and tattooing of the nipple area medically necessary. Reduction (or some cases augmentation) mammoplasty and related reconstructive procedures on the unaffected side for symmetry are also considered medically necessary.

Leeds CCGs consider breast augmentation/reconstructive surgery to enhance breast size or correct breast asymmetry including changes following pregnancy and child birth are cosmetic except where:

- Photographic evidence of the condition is required by the IFR panel – only photographs taken by medical photography will be accepted AND
- One or both breasts must be malformed:
    - Developmental failure (eg Poland Syndrome) with BMI minimum of 18.5 OR
    - Tubular breast (see http://cdn.intechopen.com/pdfs/33481/InTech-Tuberous_breast_clinical_evaluation_and_surgical_treatment.pdf

accessed July 2013) type iii with severe breast constriction with minimal breast base and hypoplasia of all four quadrants OR

- Asymmetry of more than 2 cup sizes which the IFR triage team and or panel confirms is present, AND

  - at least an estimated 40% difference (the IFR team will organise a volume scan at their discretion) AND

  - where BMI is 30 or less for at least 12 months.

  - Only the following cup sizes are recognised (see http://en.wikipedia.org/wiki/Brassiere_measurement accessed July 2013)

UK
AA
A
B
C
D
DD
E
F
FF
G
GG
H
HH
J
JJ
K

6.4 Reduction Mammoplasty (excluding gynaecomastia)

Status: not routinely commissioned - prior approval via IFR process only[1]

The NHS will only provide breast reduction for women if **all** the following criteria are met:

- The woman has received a full package of supportive care from their GP such as advice on weight loss and managing pain.

[1] https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf (accessed 05.02.19)

- In cases of thoracic/ shoulder girdle discomfort, a physiotherapy assessment has been provided
- Breast size results in functional symptoms that require other treatments/interventions (e.g. intractable candidal intertrigo; thoracic backache/kyphosis where a professionally fitted bra has not helped with backache, soft tissue indentations at site of bra straps).
- Breast reduction planned to be 500gms or more per breast or at least 4 cup sizes.
- Body mass index (BMI) is <27 and stable for at least twelve months.
- Woman must be provided with written information to allow her to balance the risks and benefits of breast surgery.
- Photographic evidence of the condition is required by the IFR panel – only photographs taken by medical photography will be accepted

6.5 Gynaecomastia Surgery

Status: not routinely commissioned[2]

Surgery for gynaecomastia is not routinely funded by the NHS. This recommendation does not cover surgery for gynaecomastia caused by medical treatments such as treatment for prostate cancer.

NHS Leeds CCGs will fund surgery for Gynaecomastia caused by medical treatments only by prior approval AND where the following criteria apply

Primary eligibility criteria:

- BMI must be 25 or less and stable for 12 months, unless a specific uncorrectable aetiological factor is identified such as androgen therapy for prostate cancer. However BMI should be 30 or less in these cases. AND
- Photographic evidence of the condition is required by the IFR panel – only photographs taken by medical photography will be accepted AND

Requests *will be rejected* prior to panel where these primary eligibility criteria are not met, unless there are very clear grounds for exception.

Other criteria considered

- Resection should be for Simon grade 2B or above (grade 2B is moderate breast enlargement with minor skin redundancy, grade 3 is gross breast enlargement with skin redundancy that simulates a pendulous female breast
- Should be for true gynaecomastia and not pseudo-gynaecomastia
- Conservative treatments have been considered, tried or have been unsuccessful
- Is causing significant patient distress through the presence of an obvious unilateral lump, abnormal appearance visible through clothing or because of pain (specifically related to the gynaecomastia) that has failed to respond to analgesia.

[2] https://www.england.nhs.uk/wp-content/uploads/2018/11/ebi-statutory-guidance-v2.pdf (accessed 05.02.19)

- Caused by a side effect of treatment of another condition such as a side effect of treatment for prostate cancer.
- The presence of unilateral gynaecomastia or marked asymmetry

Leeds CCGs will not support gynaecomastia surgery where there is evidence of on-going or recurrent use of recreational drugs or anabolic steroids.

6.6 Inverted Nipples

Status: not routinely commissioned unless associated with possible malignancy[3] - all other cases by prior approval via IFR process only

Leeds CCGs consider surgery for inverted nipples with no underlying malignancy to be cosmetic except in the following limited circumstance. All the following criteria must be met:

- Photographic evidence of the condition is required by the IFR panel – only photographs taken by medical photography will be accepted AND
- The nipple(s) must be non-retractable based on clinical examination
- The patient is post pubertal AND
- The inversion has not been corrected by correct use of a non-invasive suction device AND
- Following documented inability to breastfeed during a previous pregnancy and patient is considering a subsequent pregnancy but is not yet pregnant.

Prior approval by the IFR panel is required.

All other indications will be considered cosmetic and will not be funded unless exceptionality can be demonstrated. Surgery will not be considered prior to a first pregnancy as the risk of the procedure outweighs the risk of the nipple inversion.

6.7 Mastopexy

Status: not routinely commissioned - exceptionality approval via IFR process only

Mastopexy is not routinely commissioned.

7 Equality Impact Assessment (EIA)

This document has been assessed, using the EIA toolkit, to ensure consideration has been given to the actual or potential impacts on staff, certain communities or population groups, appropriate action has been taken to mitigate or eliminate the negative impacts and maximise the positive impacts and that the and that the implementation plans are appropriate and proportionate.

[3] https://www.nice.org.uk/guidance/NG12/chapter/Recommendations-organised-by-symptom-and-findings-of-primary-care-investigations#lumps-or-masses (accessed 7/7/16)

Include summary of key findings/actions identified as a result of carrying out the EIA. The full EIA is attached as Appendix A.

8 Implications and Associated Risks

This policy and supporting frameworks set evidence based boundaries to interventions available on the NHS. It may conflict with expectations of individual patients and clinicians.

9 Education and Training Requirements

Members of the panels will undergo training at least every three years, particularly in relation to the legal precedents around IFRs. Effective policy dissemination is required for local clinicians.

10 Monitoring Compliance and Effectiveness

Each IFR panel will maintain an accurate database of cases approved and rejected, to enable consideration of amendments to future commissioning intentions and to ensure consistency in the application of the CCGs in Leeds Commissioning Policies.

The financial impact of approvals outside of existing Service Level Agreements will be monitored to ensure the Leeds CCGs identify expenditure and ensure appropriate value for money. Member Practice clinicians need to be aware that all referrals will ultimately be a call on their own CCG budgets.

11 Associated Documentation

This policy must be read in conjunction with the underpinning Leeds CCGs decision making frameworks.

12 References and Background

Weight loss surgery
The above framework is based on the following references:

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Breast Implantation and Removal

Background

In 1992, the FDA advised that ruptured silicone implants should be removed since the health risks of extruded silicone are not known. At the same time, the FDA panel acknowledged that asymptomatic rupture may be present in up to 4% of women with silicone implants, but the FDA specifically did not recommend screening for asymptomatic ruptures.

Rupture of silicone implants can be subdivided into two categories — intra and extra capsular. After implantation, a reactive fibrous capsule is formed around the implant. If the extruded silicone is contained by this fibrous capsule the rupture is termed intracapsular. If the silicone gel is extruded beyond the capsule, the rupture is termed extracapsular. Extracapsular silicone can induce granulomatous reaction and can occasionally migrate to the axillary lymph nodes, producing a lymphadenopathy, which can mimic cancer. Clinically, extracapsular ruptures are often associated with a change in size and consistency of the breast. Extracapsular ruptures can usually be identified on mammography or other imaging studies. Research by the Department of Health concluded that there is no evidence of long term harm associated with the use of silicone gel implants. Nevertheless, an intracapsular rupture can evolve to an extracapsular rupture and the FDA has indicated that ruptured implants, whether intracapsular or extracapsular, should be explanted as well.

NHS Guidance has been developed following the breast implant scandal in relation to Poly Implant Prosthese (PiP).

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Augmentation

Background

Breast reconstruction using autologous tissue is most commonly performed using the transverse rectus abdominis myocutaneous (TRAM) flap. This flap has been in use for 20 years and has provided excellent aesthetic results. However, a drawback of the TRAM flap is related to donor site morbidity of the abdomen. The pedicle TRAM flap frequently requires use of the entire rectus abdominis muscle, while the free TRAM flap requires use of as little as a postage-stamp size portion of the muscle. Abdominal complications resulting from a sacrifice of all or a portion of the rectus abdominis muscle include a reduction in abdominal strength (10 to 50 %), abdominal bulge (5 to 20 %), and hernia (less than 5 %).

Perforator flaps have gained increasing attention with the realization that the muscle component of the TRAM flap does not add to the quality of the reconstruction and serves only as a carrier for the blood supply to the flap. Thus, the concept of separating the flap (skin, fat, artery, and vein) from the muscle was realized as a means of minimizing the morbidity related to the abdominal wall and maintaining the aesthetic quality of the reconstruction. The deep inferior epigastric perforator (DIEP) flap was introduced in the early 1990's and is identical to the free TRAM flap except that it contains no muscle or fascia. Use of this flap has been popular in the Europe for a number of years.

Deep inferior epigastric perforator flaps tend to have less robust blood flow than is typical with a standard TRAM reconstruction, so careful patient selection is important. In patients who are non-smokers, who require no more than 70 % of the TRAM flap skin paddle to make a breast of adequate size, and who have at least 1 perforating vessel greater than 1-mm in diameter with a detectable pulse, the incidence of flap complications reportedly is similar to that seen in standard free TRAM flap reconstruction.

Superior gluteal artery perforator (SGAP) flaps may be performed on women who are not candidates for a TRAM flap or who have had a failed TRAM flap. Thin women who may not have much tissue in the lower abdominal area often have an adequate amount of tissue in the gluteal region. The inferior gluteal artery perforator (SGAP) flap shares the same indications as the superior gluteal flap, namely the inability to use the TRAM flap and an abundance of soft tissue in the gluteal region.

Poland syndrome is an extremely rare developmental disorder that is present at birth (congenital). It is characterized by absence (agenesis) or under-development (hypoplasia) of certain muscles of the chest (e.g., pectoralis major, pectoralis minor, and/or other nearby muscles), and abnormally short, webbed fingers (symbrachydactyly). Additional findings may include underdevelopment or absence of 1 nipple (including the darkened area around the nipple [areola]) and/or patchy hair growth under the arm (axilla). In females, 1 breast may also be under-developed (hypoplastic) or absent (amastia). In some cases, affected individuals may also exhibit under-developed upper ribs and/or an abnormally short arm with under-developed forearm bones (i.e., ulna and radius) on the affected side. In most cases, physical abnormalities are confined to one side of the body (unilateral). In approximately 75 % of the cases, the right side of the body is affected. The range and severity of symptoms may vary from case to case. The exact cause of Poland syndrome is not known.

Autologous fat grafting (or lipomodeling) uses the patient's own fat cells to replace volume after breast reconstruction, or to fill defects in the breast following breast-conserving surgery (NICE, 2012). It can be used on its own or as an adjunct to other reconstruction techniques. The procedure aims to restore breast volume and contour without the morbidity of other reconstruction techniques. With the patient under general or local anesthesia, fat is harvested by aspiration with a syringe and cannula, commonly from the abdomen, outer thigh or flank. The fat is usually washed and centrifuged before being injected into the breast. Patients subsequently undergo repeat treatments (typically 2 to 4 sessions) (NICE, 2012). Autologous fat grafting may be delayed for a variable period of time after mastectomy. Most of the evidence for the use of autologous fat grafting in breast reconstruction is as a technique to repair contour defects and deformities. There is less information about the use of autologous fat grafting for complete breast reconstruction.

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2012) states that current evidence on the efficacy of breast reconstruction using lipomodelling after breast cancer treatment is adequate and the evidence raises no major safety concerns. The guidance noted that there is a theoretical concern about any possible influence of the procedure on recurrence of breast cancer in the long term, although there is no evidence of

this in published reports. The guidance notes that a degree of fat resorption is common in the first 6 months and there have been concerns that it may make future mammographic images more difficult to interpret.

A technology assessment on autologous fat injection for breast reconstruction prepared for the Australian and New Zealand Horizon Scanning Network (Humphreys, 2008) found that the technique has the potential to improve some contour defects; however, the results appear to be highly variable, with 2 case series finding that following autologous fat injection between 21 % and 86.5 % of patients showed substantial improvement at post-operative assessment. Patient satisfaction with the procedure was not reported. The assessment stated that longer-term follow-up is needed to determine how much of the injected fat survives and how much is eventually re-absorbed by the body. There are also important safety issues with the procedure, especially in association with the lipo-necrotic lumps that can form in the breast from the injected fat. Both case series reported this to occur in approximately 7 % of cases, and there is concern that such lumps will impede future cancer detection.

Hyakusoku et al (2009) reported several cases of complications following fat grafting to the breast. These investigators retrospectively reviewed 12 patients who had received autologous fat grafts to the breast and required breast surgery and/or reconstruction to repair the damage presenting between 2001 and 2007. All 12 patients (mean age of 39.3 years) had received fat injections to the breast for augmentation mammoplasty for cosmetic purposes. They presented with palpable indurations, 3 with pain, 1 with infection, 1 with abnormal breast discharge, and 1 with lymphadenopathy. Four cases had abnormalities on breast cancer screening. All patients underwent mammography, computed tomography, and magnetic resonance imaging to evaluate the injected fats. The authors concluded that autologous fat grafting to the breast is not a simple procedure and should be performed by well-trained and skilled surgeons. Patients should be informed that it is associated with a risk of calcification, multiple cyst formation, and indurations, and that breast cancer screens will always detect abnormalities. Patients should also be followed-up over the long-term and imaging analyses (e.g., mammography, echography, computed tomography, and magnetic resonance imaging) should be performed.

The American Society of Plastic Surgeons (ASPS) fat grafting task force (Gutowski, 2009) concluded that autologous fat grafting is a promising and clinically relevant research topic. The current fat grafting literature is limited primarily to case studies, leaving a tremendous need for high-quality clinical studies.

Mizuno and Hyakusoku (2010) stated that recent technical advances in fat grafting and the development of surgical devices such as liposuction cannulae have made fat grafting a relatively safe and effective procedure. However, guidelines issued by the ASPS in 2009 announced that fat grafting to the breast is not a strongly recommended procedure, as there are limited scientific data on the safety and efficacy of this particular type of fat transfer. Recent progress by several groups has revealed that multi-potent adult stem cells are present in human adipose tissue. This cell population, termed adipose-derived stem cells (ADSC), represents a promising approach to future cell-

based therapies, such as tissue engineering and regeneration. In fact, several reports have shown that ADSC play a pivotal role in graft survival through both adipogenesis and angiogenesis. Although tissue augmentation by fat grafting does have several advantages in that it is a non-invasive procedure and results in minimal scarring, it is essential that such a procedure be supported by evidence-based medicine and that further research is conducted to ensure that fat grafting is a safe and effective procedure.

Acellular dermal matrices are considered a standard-of-care as an adjunct to breast reconstruction. The clinical literature on acellular dermal matrix product in breast reconstruction primarily consists of single institution case series focusing on surgical technique. Much of the early literature focused on AlloDerm brand of acellular dermal matrix, since this product was first to market, but more recent literature has considered other acellular dermal matrix products. Recent literature has provided comparisons of AlloDerm to certain other acellular dermal matrix products, with the authors concluding that there is no significant difference among products (see, e.g., Ibrahim, et al., 2013; Cheng, et al., 2012). While different acellular dermal matrix products are processed differently, these appear to result in minor differences in performance in breast reconstruction.

Llewellyn-Bennett et al (2012) noted that latissimus dorsi (LD) flap procedures comprise 50 % of breast reconstructions in the United Kingdom. They are frequently complicated by seroma formation. In a randomized study, these researchers investigated the effect of fibrin sealant (Tisseel(®)) on total seroma volumes from the breast, axilla and back (donor site) after LD breast reconstruction. Secondary outcomes were specific back seroma volumes together with incidence and severity of wound complications. Consecutive women undergoing implant-assisted or extended autologous LD flap reconstruction were randomized to either standard care or application of fibrin sealant to the donor-site chest wall. All participants were blinded for the study duration but assessors were only partially blinded. Non-parametric methods were used for analysis. A total of 107 women were included (sealant = 54, control = 53). Overall, back seroma volumes were high, with no significant differences between control and sealant groups over 3 months. Fibrin sealant failed to reduce in-situ back drainage volumes in the 10 days after surgery, and did not affect the rate or volume of seromas following drain removal. The authors concluded that the findings of this randomized study, which was powered for size effect, failed to show any benefit from fibrin sealant in minimizing back seromas after LD procedures.

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Reduction Mammoplasty

Background

Reduction mammoplasty is among the most commonly performed cosmetic procedures in the UK.Reduction mammoplasty performed solely for cosmetic indications is considered not medically necessary.

Reduction mammoplasty has also been used for relief of pain in the back, neck and shoulders. Because reduction mammoplasty may be used for both medically necessary and cosmetic indications, Leeds CCGs have highlighted the above objective criteria to distinguish medically necessary reduction mammoplasty from cosmetic reduction mammoplasty.

Reduction mammoplasty has been performed to relieve back and shoulder pain on the theory that reducing breast weight will relieve this pain. For pain interventions, evidence of effectiveness from well controlled, randomised prospective clinical trials assessing effects on pain, disability, and function is limited. Well designed trials are especially important in assessing pain management interventions to isolate the contribution of the intervention from placebo effects, the effects of other concurrently administered pain management interventions, and the natural history of the medical condition. Because of their inherently subjective nature, pain symptoms are especially prone to placebo effects.

In the case of reduction mammoplasty for relief of back, neck and shoulder pain, Leeds CCGs have considered this procedure medically necessary in women with excessively large breasts because it seems logical, even in the absence of firm clinical trial evidence, that this excessive weight would contribute to back and shoulder pain, and that removal of this excessive breast tissue would provide substantial pain relief, reductions in disability, and improvements in function.

The goal of medically necessary breast reduction surgery is to relieve symptoms of pain and disability. If an insufficient amount of breast tissue is removed, the surgery is less likely to be successful in relieving pain and any related symptoms from excessive breast weight (e.g., excoriations, rash). It has been argued that reduction mammoplasty may be indicated in any woman who suffers from back and shoulder pain, regardless of how small her breasts are or how little tissue is to be removed (ASPS, 2002). The suggestion is that removal of even a few hundred grams of breast tissue can result in substantial pain relief. However, this evidence comes from observational studies (Chadbourne, et al., 2001; Kerrigan, et al., 2001). These studies did not find a relationship between breast weight or amount of

breast tissue removed and the likelihood of response or magnitude of relief of pain after reduction mammoplasty. It is not clear that breast weight would substantially contribute to back, neck and shoulder pain in women with normal or small breasts. Nor is it likely that removal of smaller amounts of breast tissue would offer significant relief of back, shoulder or neck pain. The lack of an expected "dose-response" relationship between the amount of breast tissue removed and the magnitude of symptomatic relief in these studies raises questions about the validity of these studies and the effectiveness of breast reduction as a method of relieving shoulder and back pain.

The studies used to support the arguments for the medical necessity of breast reduction surgery are poorly controlled and therefore subject to a substantial risk of bias in the interpretation of results. Well-designed, prospective, controlled clinical studies have not been performed to assess the effectiveness of surgical removal of modest amounts of breast tissue in reducing neck, shoulder, and back pain and related disability in women. In addition, reduction mammoplasty needs to be compared with other established methods of relieving back, neck and shoulder pain.

Consequently there is insufficient evidence to support the use of reduction mammoplasty, without regard to the size of the breasts or amount of breast tissue to be removed, as a method of relieving chronic back, neck, or shoulder pain.

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Gynaecomastia Surgery

Background

Gynaecomastia is common and may be asymptomatic. This disorder can lead to significant psychological stress and self-consciousness. In most cases, a thorough history and physical examination, along with limited laboratory investigations, can help to exclude breast malignancy and serious underlying endocrine or systemic disease. Careful clinical observation may be all that is required in many cases, because gynaecomastia often resolves spontaneously. Because gynecomastia is usually caused by an imbalance of androgenic and estrogenic effects on the breast, medical therapy may include antiestrogens, androgens, or aromatase inhibitors. Surgery is useful in the management of patients with long-standing symptomatic gynecomastia or when medical therapy is not successful.

Gynaecomastia may have an extrinsic cause in up to 39% of cases. Of the suspected idiopathic cases, some will be found to have an important aetiology, such as a testicular carcinoma. Selected endocrinological investigation is important.

Patients who are on medication that may cause gynaecomastia may not always be able to have that medication stopped. Furthermore, withdrawal of the medication may not always be associated with resolution of the gynaecomastia. There are at least 69 drugs that are known to be associatied with gynaecomastia.

Treatments for painful or embarrassing gynaecomastia include an anti-oestrogen, such as tamoxifen (unlicensed indication), or surgery (liposuction or mammoplasty). However, although idiopathic gynecomastia is highly prevalent with hundred of millions of affected men, unfortunately, there is no proven medical therapy for this condition and the quality of the research using medications is very poor. As an example, the best publications available, for tamoxifen include only 332 individuals and of those only 10 (<3%) were studied in randomized trials.

The clinical classification of gynaecomastia, developed by Simon et al is the most commonly used classification and helps to understand the surgical correction of gynaecomastia. This classification is based on the extent of breast enlargement and the presence or absence of excess skin:

- Grade 1: minor breast enlargement with no excess skin;
- Grade 2A: moderate breast enlargement with no excess skin;
- Grade 2B: moderate breast enlargement with excess skin;
- Grade 3: marked breast enlargement with excess skin.

Patients with grades 1 and 2A gynaecomastia require no skin excision, but glandular excision alone. The breast development associated with grades 2B and 3 is so marked that excess skin must be removed. Although this classification is not applicable to the surgical management of men with breast cancer and gynaecomastia, it allows important management decisions to be made for the surgical correction of gynaecomastia.

An alternative classification, relates to the position of the nipple-areola complex: when the nipple-areola complex is above the inframammary fold (grade I and grade II gynaecomastia), complete flattening of the thorax can be achieved by means of suction or ultrasound-assisted lipectomy and skin-sparing adenectomy. When the nipple-areola complex is at the same height as, or at most 1cm below the fold (grade III gynaecomastia), skin-sparing techniques are no longer sufficient to flatten the thorax, and it becomes necessary to remove the redundant skin by means of periareolar removal of epidermis. In cases of marked ptosis, when the nipple-areola complex is

more than 1cm below the fold (grade IV gynaecomastia), reduction mastoplasty becomes necessary, with upper repositioning of the nipple-areola complex; in these cases central pedicle techniques make it possible to limit scarring in the periareolar area.
Surgical excision is justified where the breast specialist has assessed the patient and recommended such an approach. Such a decision may be based on many factors. They include the rare concern that there may be an underlying male breast cancer. Cancer phobia is not uncommon in this regard. Conventional treatment of the complaint of an unresolving male breast lump remains surgical excision, and most patients may be discharged subsequently without the need for further follow-up.
In addition, there will remain a need for this procedure in patients who have had funded treatment for morbid obesity who achieve massive weight loss where there are functional or significant psychological problems associated with such weight loss. The male breast, a body-region that symbolizes manhood and strength and often remaining as a deflated skin-envelope, is one of the most disturbing body regions, causing extreme lack of confidence in post-weight-loss patients.
Surgical excision allows evaluation of the entire tissue component such that cancerous or precancerous lesions may be identified, which although rare, continue to be reported.
The increased use of antiandrogens as monotherapy for prostate cancer is leading to an increase in the number of patients affected by gynaecomastia, and surgical excision is likely to be the most appropriate treatment where assessed as such by a breast specialist.
In cases of idiopathic gynaecomastia that do not resolve after a period of 12-24 months, acceptable resolution has been achieved with surgical excision.
Surgery should only be carried out by and after review by a specialist with specific experience in this condition to recuce the potential risk of unsatisfactory surgical results.
Men under the age of 25-years should predominantly be managed conservatively as the majority of such cases resolve.

The above framework is based on the following references:

1. No author listed. Gynaecomastia. GP Notebook. Cambridge, UK: Oxbridge Solutions, Ltd.; 2003. Available at: http://www.gpnotebook.co.uk/simplepage.cfm?ID=-1858797563&linkID=13174&cook=yes . Accessed July 2013.
2. Autorino R, Perdona S, D'Armiento M, et al. Gynecomastia in patients with prostate cancer: Update on treatment options. Prostate Cancer Prostatic Dis. 2006;9(2):109-114.
3. Henley DV, Lipson N, Korach KS, Bloch CA. Prepubertal gynecomastia linked to lavender and tea tree oils. N Engl J Med. 2007;356(5):479-485
4. Narula HS, Carlson HE. Gynecomastia. Endocrinol Metab Clin North Am. 2007;36(2):497-519.
5. Handschin AE, Bietry D, Hüsler R, et al. Surgical management of gynecomastia—a 10-year analysis. World J Surg. 2008;32(1):38-44.
6. Leclère FM, Spies M, Gohritz A, Vogt PM. Gynecomastia, its etiologies and its surgical management: A difference between the bilateral and unilateral cases? Ann Chir Plast Esthet. 2008;53(3):255-261.
7. Devalia HL, Layer GT. Current concepts in gynaecomastia. Surgeon. 2009;7(2):114-119.
8. Petty PM, Solomon M, Buchel EW, Tran NV. Gynecomastia: Evolving paradigm of management and comparison of techniques. Plast Reconstr Surg. 2010;125(5):1301-1308.
9. Laituri CA, Garey CL, Ostlie DJ, et al. Treatment of adolescent gynecomastia. J Pediatr Surg. 2010;45(3):650-654.

10. He Q, Zheng L, Zhuang D, et al. Surgical treatment of gynecomastia by vacuum-assisted biopsy device. J Laparoendosc Adv Surg Tech A. 2011;21(5):431-434.
11. Li CC, Fu JP, Chang SC, Chen TM, Chen SG. Surgical treatment of gynecomastia: complications and outcomes. Ann Plast Surg. 2012;69:510-5
12. Simon B.B., Hoffman S., Kahn S.: Classification and surgical correction of gynecomastia. Plast. Reconstr. Surg., 51: 48-52, 1973.

Inverted nipples

This policy is informed by local clinical consensus.

Appendices

A Equality Impact Assessment

Title of policy	Aesthetic Breast Procedures	
Names and roles of people completing the assessment	Fiona Day Consultant in Public Health Medicine, Helen Lewis, Head of Acute Provider Commissioning	
Date assessment started/completed	26.6.16	25.7.16

1. Outline	
Give a brief summary of the policy	The purpose of the commissioning policy is to enable officers of the Leeds CCGs to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs. This policy relates to requests for aesthetic breast procedures.
What outcomes do you want to achieve	We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness.

2. Evidence, data or research	
Give details of evidence, data or research used to inform the analysis of impact	See list of references

3. Consultation, engagement	
Give details of all consultation and engagement activities used to inform the analysis	Discussion with clinicians and patient representatives on the principles of decision making. Discussion with patient leaders relating to changes in the content of the policy and advice on proportionate engagement.

of impact	The policy review was undertaken using any updated NICE or equivalent guidance, and input from clinicians was sought where possible. Engagement sessions with patient leaders were undertaken and all policies individually reviewed. Patient leaders were satisfied with the process by which the policy was developed, particularly in light of the robust process (including extensive patient engagement) by which NICE guidance are developed, and acknowledging their own local role in providing assurance. No concerns were raised with regard to the policy. Local clinical commissioning and clinical providers have had the opportunity to comment on the draft policies.

4. Analysis of impact			
This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to; eliminate unlawful discrimination; advance equality of opportunity; foster good relations			
	Are there any likely impacts? **Are any groups going to be affected differently?** **Please describe.**	**Are these negative or positive?**	**What action will be taken to address any negative impacts or enhance positive ones?**
Age	Yes. However the age criteria is considered a justifiable proxy for physical/psychological maturity.		
Carers	No		
Disability	No		
Sex	Different surgical procedure with different thresholds for interventions and these are not based on gender, but on the clinical evidence for each procedure.		
Race	No		
Religion or	No		

belief			
Sexual orientation	No		
Gender reassignment	No		
Pregnancy and maternity	Inverted nipple treatment is only available to support breast feeding in specific circumstances.		
Marriage and civil partnership	No		
Other relevant group	No		
If any negative/positive impacts were identified are they valid, legal and/or justifiable? **Please detail.**			

5. Monitoring, Review and Publication			
How will you review/monitor the impact and effectiveness of your actions	Annual report of IFR activity reported through relevant committees to Governing Bodies of the 3 CCGs. A limited equity audit is undertaken as part of this. Complaints and appeals monitoring.		
Lead Officer	Simon Stockill	**Review date:**	Dec 2019

6.Sign off			
Lead Officer			
Director on behalf of the 3 Leeds CCG Medical Directors	Dr Simon Stockill, Medical Director, Leeds West CCG	**Date approved:**	24.8.16

B Policy Consultation Process:

Title of document	Aesthetic Breast Procedures Policy
Author	F Day
New / Revised document	Revised
Lists of persons involved in developing the policy	F Day Consultant in Public Health Medicine, Leeds City Council Donald Dewar, Consultant Plastic Surgeon, LTHT
List of persons involved in the consultation process:	See appendix A

C Version Control Sheet

Version	Date	Author	Status	Co
V1	7/7/16	F Day	draft	Addition of NICE guideline as reference in inverted nipples
V3	18.10.17	F Day	Amendment	Addition of : Asymmetry of more than 2 cup sizes which the IFR triage team and or panel confirms is present, AND • at least an estimated 40% difference (the IFR team will organise a volume scan at their discretion) AND • where BMI is 30 or less for at least 12 months.
V4	5.2.19	F Day	Amendment	Changes to breast reduction in men and women in line with NHSE Evidence Based Interventions : Response to the public consultation and next steps – November 28th 2018