GMCA GREATER MANCHESTER COMBINED AUTHORITY

NHS in Greater Manchester

Greater Manchester EUR Policy Statement on:

Aesthetic Breast Surgery

GM Ref: GM006-GM010

Version: 3.5 (23 January 2019)

Commissioning Statement

Aesthetic Breast Surgery	
Policy Exclusions **(Alternative commissioning arrangements apply)**	Reconstructive surgery following cancer, trauma or another significant clinical event is not covered by this policy and is routinely commissioned across Greater Manchester. Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).
Our definition of Aesthetic	All surgery involving incision into healthy tissue, in this case a healthy breast whatever its size and shape, is considered to be aesthetic. This includes cases where there are symptoms, external to the breast, that are attributed to, or exacerbated by, the size of the breast(s).
Policy Inclusion Criteria	**Breast Augmentation** All surgery involving incision into healthy tissue in this case a healthy breast whatever its size and shape is considered to be aesthetic. Surgery to augment the size and or shape of a breast(s) is **not** routinely commissioned, with the exception of proven amastia or amazia. There should be confirmation either in the form of a consultant letter or an ultrasound report that there is an absence of breast tissue. This policy applies equally to all women including those who have completed gender realignment. The period of oestrogen therapy on the realignment pathway is considered, for the purposes of this policy, to equate to the period of hormonal increase experienced in puberty. Non-response to this therapy will be considered to be amazia. **NOTE:** • In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for **all** applications relating to the female breast, measurements **must** be submitted using either method in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. **Applications using other methods will not be accepted**. • The patient **must** have completed puberty **Funding Mechanism** Individual prior approval provided the patient has proven amastia or amazia. Requests must be submitted with all relevant supporting evidence. Clinicians can submit an individual funding request outside of this guidance if they feel there is a good case for clinical exceptionality. Requests must be submitted with all relevant supporting evidence. **Revision of Breast Augmentation** Surgery is **not** routinely commissioned, however the NHS has a general duty of care and if there is a health risk associated with implants, funding will be provided for their removal only unless the original implant surgery was NHS funded; in which case funding will be available for removal and replacement. The Department of Health advice on Poly Implant Prothèse (PIP) implants

recommends that where woman who has PIP implants decides, with her doctor, that in her individual circumstances she wishes to have her implants removed, her healthcare provider should support her in carrying out this surgery. Where her original provider is unable or unwilling to help, the NHS will remove but not normally replace the implant. With this in mind the removal of any faulty prosthesis implanted privately will be funded by the local NHS but the NHS will not normally fund their replacement. To avoid creating asymmetry the non-faulty implant may be removed at the same time.

NOTE:

- In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for **all** applications relating to the female breast, measurements **must** be submitted using either method in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. **Applications using other methods will not be accepted**.
- The patient **must** have completed puberty

Funding Mechanism

Individual prior approval provided the patient meets the above criteria. Requests must be submitted with all relevant supporting evidence.

Clinicians can submit an individual funding request outside of this guidance if they feel there is a good case for clinical exceptionality. Requests must be submitted with all relevant supporting evidence.

Breast Reduction

All surgery involving incision into healthy tissue in this case a healthy breast whatever its size and shape is considered to be aesthetic.

Breast reduction surgery is **not** routinely commissioned.

If applying for funding on the grounds of clinical exceptionality the following standard set of information will need to be provided in addition to the individual clinical exceptional circumstances. ***Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality:***

- In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for **all** applications relating to the female breast, measurements **must** be submitted using either method in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. **Applications using other methods will not be accepted**.
- Confirmation that a correctly fitted bra has been worn for a period of at least 6 months and has not relieved the symptoms.
- Evidence of a history of intertrigo, if applicable, its frequency and medication used.
- Where the patient has reported back and neck pain, evidence that a course of physiotherapy has been completed without improvement of symptoms.
- The patient's height and weight records for the previous 2 years (or, if this is not available, a statement from the clinician that their weight has been stable for at least 2 years). This must include the patient's current height and weight (BMI must be less than 30).
- Patients **must** be advised that if they go on to have further children they may develop further aesthetic problems with the breasts and it is unlikely that further aesthetic breast surgery would be funded on the NHS.
- Non-identifiable photographs, preferably medical illustrations if available, will be

requested, to support the decision making process, but will not form the sole basis of the decision. It is not mandatory for photographs to be provided by a patient.

- The patient **must** have completed puberty

Funding Mechanism

Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

Breast Asymmetry

All surgery involving incision into healthy tissue in this case a healthy breast whatever its size and shape is considered to be aesthetic.

- Surgery is only commissioned where there is a difference in breast size of 3 cups (i.e. there should be at least 2 cup sizes between the sizes given for each breast). ***For example:*** *the difference between a B cup on one side and a DD on the other is 3 cup sizes with 2 cup sizes in between: B to (C to D) to DD.*

  The application should include current band and cup measurements for both breasts. In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for **ALL** applications relating to the female breast, measurements **must** be submitted using **Method 1** in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. **Applications using other methods will not be accepted**.
- The patient **must** have completed puberty
- The application should also include the patient's height and weight records for the previous 2 years (or, if this is not available, a statement from the clinician that their weight has been stable for at least 2 years). This must include the patient's current height and weight (BMI must be less than 30).

NOTE:

- Due to the risks and long term implications relating to breast implants, **surgery to reduce the larger breast only will be approved.**
- Requests made by clinicians to enhance the smaller breast, will be considered under clinical exceptionality. This includes, but is not limited to, cases where reduction to the size of the larger breast would leave the women with a bust size disproportionate to her frame.
- The outcome of reduction surgery can be affected by the individual's weight and how stable that weight is, which is why this information is requested.

If applying for funding on the grounds of clinical exceptionality the following standard set of information will need to be provided in addition to the individual clinical exceptional circumstances. ***Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality***:

- Current band and cup measurements for both breasts. In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for **ALL** applications relating to the female breast, measurements **must** be submitted using **Method 1** in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. **Applications using other methods will not be accepted**.
- The patient's height and weight records for the previous 2 years (or, if this is not available, a statement from the clinician that their weight has been stable for at least 2 years). This must include the patient's current height and weight (BMI must

be less than 30).

- Non-identifiable photographs, preferably medical illustrations if available, will be requested, to support the decision making process, but will not form the sole basis of the decision. It is not mandatory for photographs to be provided by a patient.
- The patient **must** have completed puberty

Funding Mechanism

Individual prior approval provided the patient has a difference in breast size of 3 cups or more, in line with the above criteria. Requests must be submitted with all relevant supporting evidence.

Clinicians can submit an individual funding request outside of this guidance if they feel there is a good case for clinical exceptionality OR if an enlargement to the smaller breast is being requested. Requests must be submitted with all relevant supporting evidence.

Breast Lifts (Mastopexy)

All surgery involving incision into healthy tissue in this case a healthy breast whatever its size and shape is considered to be aesthetic.

Mastopexy surgery is **not** routinely commissioned, unless part of an approved breast reduction procedure.

Funding Mechanism

Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

Gynaecomastia (Adult)

All surgery involving incision into healthy tissue in this case a healthy breast whatever its size and shape is considered to be aesthetic.

Gynaecomastia surgery is **not** routinely commissioned.

If applying for funding on the grounds of clinical exceptionality the following standard set of information will need to be provided in addition to the individual clinical exceptional circumstances. ***Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality:***

- Evidence that pseudo-gynaecomastia has been ruled out.
- Underlying medical conditions have been ruled out.
- There is no history of steroid overuse.
- No history that it is caused by a side effect of a drug.
- The patient's height and weight records for the previous 2 years (or, if this is not available, a statement from the clinician that their weight has been stable for at least 2 years). This must include the patient's current height and weight (BMI must be 25 or below).
- Clinical confirmation of the grade of gynaecomastia.
- Non-identifiable photographs, preferably medical illustrations if available, will be requested, to support the decision making process, but will not form the sole basis of the decision. It is not mandatory for photographs to be provided by a patient.
- The patient **must** have completed puberty

Adolescent Gynaecomastia

All surgery involving incision into healthy tissue in this case a healthy breast whatever its size and shape is considered to be aesthetic.

Adolescent gynaecomastia surgery is **not** routinely commissioned.

If applying for funding on the grounds of clinical exceptionality the following standard set of information will need to be provided in addition to the individual clinical exceptional circumstances. ***Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality:***

- All potential underlying causes of gynaecomastia been investigated and either ruled out or treated
- The individual does not have excess body fat (preferably a BMI less than 25)
- The individual has been followed up for the appropriate length of time required to allow gynaecomastia of puberty to resolve. **NOTE:** this does **not** mean that puberty must be completed.
- The individual has grade 2b or 3 gynaecomastia
- They have been fully informed of the risk of scarring and nipple 'displacement' if they continue to grow after surgery **OR** confirmation that the adolescent (final) growth spurt has definitely been completed

NOTE: A mastectomy procedure for patients going through female to male gender realignment falls under the commissioning responsibility of NHS England. Please refer to NHS England's Interim Gender Dysphoria Protocol and Service Guideline 2013/14.

Funding Mechanism

Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

Inverted Nipple Correction

Idiopathic nipple inversion can often (but not always) be corrected by the application of sustained suction. Commercially available devices may be obtained from major chemists or online without prescription for use at home by the patient. Greatest success is seen if it is used correctly for up to three months.

Nipple inversion may occur as a result of an underlying breast malignancy and it is essential that this be excluded. An underlying breast cancer may cause a previously normally everted nipple to become indrawn: this must be investigated urgently.

Surgical correction of nipple inversion is **not** routinely commissioned.

If applying for funding on the grounds of clinical exceptionality the following standard set of information will need to be provided in addition to the individual clinical exceptional circumstances. ***Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality:***

- Evidence that underlying breast malignancy / breast cancer has been ruled out
- Evidence that the inversion has not been corrected by correct use of a non-invasive suction device (used for at least 3 months)
- The patient is post-pubertal and there is a functional need for nipple inversion to be corrected i.e. for breast feeding

	• Non-identifiable photographs, preferably medical illustrations if available, will be requested, to support the decision making process, but will not form the sole basis of the decision. It is not mandatory for photographs to be provided by a patient. **Funding Mechanism** Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.
Clinical Exceptionality	Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality. Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is: • Significantly different to the general population of patients with the condition in question. ***and as a result of that difference*** • They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.
Fitness for Surgery	The clinician making the request must confirm that in their opinion the patient is fit for the surgery requested.
Best Practice Guidelines	All providers are expected to follow best practice guidelines (where available) in the management of these conditions.

Contents

Policy Statement

Greater Manchester Health and Care Commissioning (GMHCC) Effective Use of Resources (EUR) Policy Team, in conjunction with the GM EUR Steering Group, have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMHCC/GM EUR Steering Group have reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

Equality & Equity Statement

GMHCC/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMHCC/CCGs are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMHCC/CCGs will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMHCC EUR Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMHCC evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact policyfeedback.gmscu@nhs.net.

Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Joint Commissioning Board (GMJCB) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the GM EUR Operational Policy.

Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

Rationale behind the policy statement

Aesthetic breast surgery is not clinically indicated and carries risks associated with the surgery and risks of complications following surgery. This policy is based on an assessment of that risk and of the cost implications of these procedures, their complications and need for revision.

Treatment / Procedure

There are an increasing number of requests for aesthetic breast surgery across Greater Manchester for reasons that are more aesthetic than clinical.

The procedures requested include:

- Breast Augmentation
- Breast Reduction both female and male (for Gynaecomastia)
- Breast Lift / Mastopexy
- Inverted nipple correction
- A combination of the above to address asymmetry

Aesthetic breast surgery covers those requests where there is no underlying breast disease that is being treated by the surgery.

Applications often include reference to concurrent health issues e.g. back pain, as part of the request.

Large Breasts

In medicine, there are many different standards on large breast size - large breast size can be divided into two categories: the bra size and the cup size. A measure of “largeness” could be the relative variation between the band size and the cup size, i.e. a 32HH will appear disproportionately larger than a 40HH. The risk of complications following breast surgery are greater when the BMI is over 30.

Droopy / Pendulous Breasts

Droopy or pendulous breast can occur at any size (for large breasts surgical lifts are often performed alongside a reduction as the heavy breast will cause drooping to recur). Droopiness of the breast is a common legacy of motherhood, weight loss or ageing.

Small Breasts

There is no standard definition of small breasts and there are no medical reasons for increasing the size of small but normal breasts and breast implants carry a risk of complications, (in addition to the risks of any surgical procedure) and on average last for approximately 10 years.

Amastia (and Amazia)

Is the absence of breast tissue (classified as amastia where the nipple is absent as well) so that there is no development at puberty. Rarely this can be bilateral but is often unilateral and can be associated with other congenital issues, e.g. Poland’s syndrome.

Breast Asymmetry

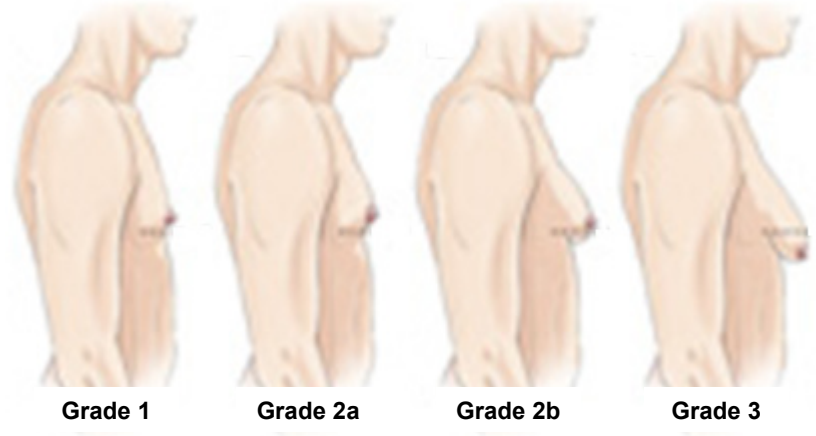
Breast size asymmetry is when a woman's breasts are different in size and is defined as a difference of form, position, or volume of the breast. Many women have a degree of asymmetry but at what stage does this become “abnormal”. For the purposes of this policy asymmetry is defined as a difference of 3 or more cup sizes.

Gynaecomastia

Gynaecomastia is the development of abnormally large mammary glands in males resulting in breast enlargement. Pseudo-gynaecomastia and underlying pathology need to be excluded before considering surgical intervention.

Simon et al. (Simon BE, Hoffman S, Kahn S. Classification and surgical correction of gynecomastia Plast Reconstr Surg . 1973;51:48) divided gynecomastia into four grades as follows:

- **Grade 1:** Small enlargement, no skin excess
- **Grade 2a:** Moderate enlargement, no skin excess
- **Grade 2b:** Moderate enlargement with extra skin
- **Grade 3:** Marked enlargement with extra skin



Nipple inversion

Nipple inversion is where the nipple is retracted into the breast, instead of protruding outwards. Nipple inversion can affect one or both breasts.

Epidemiology and Need

There are no readily available statistics on the incidence of non-cancerous breast conditions but requests for the surgery to correct them is increasing across Greater Manchester.

Adherence to NICE Guidance

NICE have not currently issued guidance on this treatment.

Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

Date of Review

Two years from the date of the last review, unless new evidence is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

Glossary

Term	Meaning
Amastia	Congenital absence of breast tissue and nipple.
Amazia	Congenital absence of breast tissue.
Augmentation	Increasing the size of the breast through the insertion of a prosthetic breast (implant) or fat transfer.
Exceptionality	A person to which the general rule is not applicable (see policy exclusions sections above for a detailed definition).
Gynaecomastia	Male breast enlargement.
Mastopexy	Up-lifting of droopy breast.
Poland's syndrome	A disorder in which affected individuals are born with missing or abnormal muscles on one side of the chest wall. Most individuals with Poland syndrome also have abnormalities of the hand.
Reduction	Removal of excess fat and skin from the breasts.

References

1. GM EUR Operational Policy
2. NHS Modernisation Agency: Information for Commissioners of Plastic Surgery Services – Referrals and Guidelines in Plastic Surgery
3. Royal College of Surgeons: Commissioning Guide – Breast Reduction Surgery, May 2014
4. NHS England: Interim Clinical Commissioning Guide – Breast Asymmetry Correction Surgery, November 2013
5. NHS England: Interim Clinical Commissioning Guide – Breast Reduction and Breast Lift (mastopexy) Surgery, November 2013
6. Kinesiology statements regarding breast size and back and neck pain
7. Chiropracty statement regarding ill-fitting bras and back and neck pain
8. British Association of Aesthetic Plastic Surgeons (BAAPS) papers on:
    - Breast Augmentation (Enlargement)
    - Breast Reduction (Mammoplasty)
    - Breast Uplift (Mastopexy)
    - Fat transfer to Breast
    - Gynecomastia (Male breast reduction)
9. Factors Associated with Readmission following Plastic Surgery: A Review of 10,669 Procedures from the 2011 American College of Surgeons National Surgical Quality Improvement Program Data Set, Fischer, J P, et al. Plastic & Reconstructive Surgery. 132(3):666-674, September 2013.

10. Poly Implant Prothèse (PIP) breast implants: final report, Department of Health, 18 June 2012
11. US Food & Drug Administration: Breast Implants

Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	04/02/2014
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	11/03/2014
Greater Manchester Association Governing Group	01/04/2014
Bolton Clinical Commissioning Group	02/05/2014
Bury Clinical Commissioning Group	04/06/2014
Heywood, Middleton & Rochdale Clinical Commissioning Group	16/05/2014
Central Manchester Clinical Commissioning Group	02/07/2014
North Manchester Clinical Commissioning Group	14/05/2014
Oldham Clinical Commissioning Group	05/06/2014
Salford Clinical Commissioning Group	11/07/2014
South Manchester Clinical Commissioning Group	25/06/2014
Stockport Clinical Commissioning Group	14/05/2014
Tameside & Glossop Clinical Commissioning Group	21/05/2014
Trafford Clinical Commissioning Group	15/07/2014
Wigan Borough Clinical Commissioning Group	21/05/2014

Appendix 1 – Evidence Review

Aesthetic Breast Surgery
GM006-GM010

Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College websites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

Database	Result
York	Breast Reduction Surgery for Hypermastia: Clinical Effectiveness and Guidelines, Rapid Response Report: Summary of Abstracts, Canadian Agency for Drugs and Technologies in Health, 21st August 2014 (Added at review: April 2015)
BMJ Best Practice	Information on excluding and managing underlying causes of gynaecomastia BMJ Best Practice website - Gynaecomastia
General Search (Google)	BAPRAS/Royal College of Surgeons, Commissioning Guide: Breast reduction surgery 2014
	NHS England Interim Clinical Commissioning Policy: Breast Asymmetry Correction Surgery, November 2013
	NHS England Interim Clinical Commissioning Policy: Breast Reduction and Breast Lift (Mastopexy) Surgery, November 2013
Medline	Developing Asymmetric Breast Tissue, Catherine W. Piccol et al April 1999 Radiology, 211, 111-117
	Evaluation of professional bra fitting criteria for bra selection and fitting in the UK, J. White & J. Scurr pages 704-711 Ergonomics Volume 55, Issue 6, 2012
	Health Care Utilization Among Women Who Have Undergone Breast Implant Surgery, Tweed, A. (2003), The British Columbia Centre of Excellence for Women's Health (BCCEWH)
	The impact of obesity on breast surgery complications, Chen, C L., Plast Reconstr Surg. 2011 Nov; 128(5):395e-402e. doi: 10.1097 / PRS.0b013e3182284c05
	Factors Associated with Readmission following Plastic Surgery: A Review of 10,669 Procedures from the 2011 American College of Surgeons National Surgical Quality Improvement Program Data Set, *Plast. Reconstr. Surg.* 132: 666, 2013.
	Gynecomastia: Pathophysiology, Evaluation, and Management, *Mayo Clin Proc.* 2009;84(11):1010-1015
	Risk Factors for Complications Following Breast Reduction: Results from a Randomized Control Trial, Srinivasaiah, N. et al. 2014, The Breast Journal, Volume 20 Number 3, 274–278 (Added at review: April 2015)
	An Outcomes Analysis of 2142 Breast Reduction Procedures, Manahan, M.A. et al 2015, Annals of Plastic Surgery, Volume 74 No.3, 289 – 292 (Added at review: April 2015)

	Risk factors for complications after breast reduction surgery, Lewis R. et al 2014, Journal of Plastic Surgery & Hand Surgery, Volume 48, 10-14 (Added at review: April 2015)
	Inverted nipple repair revisited: a 7-year experience, Gould D.J. et al 2015, Aesthetic Surgery Journal, Volume 35, No. 2, 156-164 (Added at review: May 2015)

Summary of the evidence

Limited evidence was found in the medical literature for the impact of large breasts on health – specifically back and neck pain.

One rapid review of the evidence that hypermastia causes neck, shoulder, or upper back pain in adult women identified one systematic review, three non-randomized studies regarding breast reduction surgery for hypermastia. The identified systematic review found that women who underwent breast reduction surgery had improved outcomes regarding musculoskeletal pain, breathing, sleep, and headaches. One non-randomized study found that women who had larger breast tissue resection volumes had more often experienced pre-operative back pain, breast pain, shoulder grooves, rashes under the breasts, poor posture, and exercise intolerance than those who went on to have smaller resections; however, symptoms improved in both groups postoperatively. All data in this retrospective cohort study were collected retrospectively, therefore the results may be affected by recall bias. The authors concluded that breast reduction surgery improved a variety of symptoms, regardless of body surface-area calculated adjustments and breast tissue resection volume. The remaining two non-randomized studies also found a postoperative improvement in breast-related symptoms, including quality of life, frequency of pain, and low-back compressive forces. These were small cohort studies, one using data from 59 patients, and the other 11 patients only.

Kinesiology links large breasts with neck and back pain but equally chiropracty links it to ill-fitting bras plus one ergonomics study (see below supporting correctly fitted bras for larger women).

No evidence that small breasts have a direct impact on health.

Moderate to good evidence found that obesity and current smoking impact on the outcome of surgery – particularly in breast reduction surgery.

No evidence that inverted nipples have a direct impact on health. Commissioning guidance acknowledges functional difficulties in breast feeding with inverted nipples.

Last updated: May 2015

The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

1. LEVEL 4: CASE SERIES

Developing Asymmetric Breast Tissue, Catherine W. Piccol et al April 1999 Radiology, 211, 111-117

ABSTRACT

Purpose: To show that benign asymmetric breast tissue detected mammographically may increase over time.

Materials and methods: Serial mammograms obtained in 21 women with negative physical examination results and mammographically detected developing asymmetric breast tissue were reviewed, and findings were correlated with results of biopsy (*n* = 16), ultrasonography (US) (*n* = 8), and contrast material–enhanced magnetic resonance (MR) imaging (*n* = 3). Five patients who did not undergo biopsy were followed up for 13–84 months. Thirteen of 16 biopsy specimens were reviewed.

Results: At the time of mammographic change, 12 patients without baseline asymmetric tissue had a mean age of 41.7 years and a mean size of asymmetric tissue of 2.4 cm. The mean age of nine patients with baseline asymmetric tissue was 46.9 years. In eight patients, the mean size increase was 2.5 cm. One patient showed increased tissue density but stable size. All US and MR images were negative. Pseudoangiomatous stromal hyperplasia was present in all 13 biopsy specimens reviewed and extensive in 12. No malignancies have been reported in five of the followed-up patients, and two have had continued enlargement of asymmetric tissue.

Conclusion: Pseudoangiomatous stromal hyperplasia is a common histopathologic finding in developing asymmetric breast tissue. Follow-up, rather than biopsy, is a management option if benign imaging and clinical criteria are met.

2. LEVEL 4: CASE SERIES

Evaluation of professional bra fitting criteria for bra selection and fitting in the UK, J. White & J. Scurr pages 704-711 Ergonomics Volume 55, Issue 6, 2012

A correctly fitting bra is essential for good health; this study investigates the use of professional bra fitting criteria to establish best-fit in an underwire bra commonly sold in the UK. A comparison was made between women's bra size as measured by the traditional bra fitting method with their recommended bra size based on professional bra fitting criteria. Forty-five female participants were recruited; their mode self-reported bra size was 34DD. Participants were measured in their own bra using the traditional bra-fitting method to establish their 'traditional size'. A 'best-fit' bra size was recorded for participants based on professional bra fitting criteria. Significant differences were found between traditional and best-fit cup and band sizes ($p < 0.001$); the traditional method of bra fitting overestimated band size and underestimated cup size. As band size increased the traditional method also became more inaccurate ($p < 0.001$). It is recommended that women are educated in assessing their own bra fit using professional bra fitting criteria and less emphasis placed on determining absolute bra size.

Practitioner Summary: This is the first study to investigate using professional bra fitting criteria to establish best-fit in an underwired bra commonly sold in the UK. The traditional method of bra fitting was found to be inadequate, especially for larger-breasted women; the use of professional bra fitting criteria should be encouraged.

3. LEVEL 1: REVIEW

Health Care Utilization Among Women Who Have Undergone Breast Implant Surgery, Aleina Tweed, from the British Columbia Centre of Excellence for Women's Health

Health Complications from Breast Implant Surgery Common

For decades, women who have undergone breast implant surgery have reported high implant failure rates and general, unidentifiable illness. In 1992, silicone gel-filled implants were subject to government moratoriums in the United States and in Canada, until such time as their safety could be assured. In the years that have followed, researchers have tried to find answers. In the meantime, breast implantation continues to become more and more popular, with saline-filled implants taking the place of their silicone predecessors.

Many women who choose breast implantation are very happy with the results of their surgery. They report psychological and emotional benefit from their new body image. However, many women report side-effects and feel that their short-term and long-term health has been compromised.

In Canada, thousands of women have chosen breast implant surgery, including an estimated 25,000 or more in British Columbia alone. As in all of North America, approximately 20% of these surgeries are for reconstruction after cancer or prophylactic mastectomy, or to correct under- or non-developed breasts. The other 80% are performed as cosmetic augmentation. Such surgery is not considered "essential" and is therefore paid for privately rather than through public insurance. However, if there are health consequences to this surgery – ranging from the well established local complications to the very controversial systemic complications – these women enter the public health care system for their care.

Breast implant research is beset by challenges, not the least of which is the lack of a central registry allowing health care professionals or researchers to track women who receive breast implants or to do any follow-up. But we do know that a very high number of women have been affected by breast implant-related complications. A Mayo Clinic study in the United States, for example, found that 25% of women with breast implants suffered local complications requiring additional surgery within five years. We also know that there were 103,343 adverse reaction reports associated with silicone breast implants and 23,454 reports involving saline implants received by the U.S. Food and Drug Administration between January 1, 1985 and September 17, 1996.

In a recent study, researchers at the BC Centre of Excellence for Women's Health have discovered relatively high complication rates for breast implantation in Canada as well. Data collected from a study group of 147 women who had undergone breast implant surgery were compared to data from a non-implant comparison group (583 women). Researchers found that women who have or have had breast implants visited doctors and specialists significantly more than women who had not undergone implant surgery. The study also indicated that women with breast implants were more than four times as likely to be hospitalized, and that the number of hospitalizations they experienced over the study period was significantly higher than among women without implants.

The researchers also found that over half (51%) of respondents from the study group reported at least one additional breast-implant related surgery subsequent to the initial implantation. Of those, half (49%) had undergone one additional surgery, 23% had undergone two, 11% had undergone three, and 17% had undergone four or more additional surgeries. For some of these women, the complications were enough to convince the women that they no longer wanted breast implants. 40% of respondents had had their implants permanently removed.

Breast implant surgery is not deemed medically necessary and is performed – and paid for – privately in the vast majority of cases. However, it appears to directly contribute to an increased need for public health care services among the women receiving these devices. If, as the literature suggests, serious local complication rates are at least 25% – and more likely are 50% or higher – there are many thousands of women in Canada who are using greater health care resources as a result of this surgery, and whose health and well-being may be at risk.

Complications with Breast Implantation

There are three major groups of health complications associated with breast implants: local complications, systemic complications and psychological complications. Breast implant surgery also carries the same risks associated with any surgical implantation of a medical device. All aesthetic complications (dissatisfaction with size, position, etc., of the implants) are not funded by public health care; however, all health complications resulting from the implant, including the removal of the implants, is covered by publicly funded health care.

1. *Surgical complications*

Any surgery – and breast implantation is no different – involves risks such as complications of general anesthesia, infection, haematoma, hemorrhage, thrombosis, skin necrosis, delayed wound healing and additional surgeries.

A woman who receives breast implant(s) will likely require additional surgery or surgeries related to her implant(s) over her lifetime. These procedures may include treatment of capsular contracture, correction of the implant's size or position, infection control as the result of other local or systemic complications, or to prevent or treat leakage, rupture or other health problems.

2. *Local complications*

Local complications can range from very mild to very severe, and they affect a large percentage of women who undergo breast implant surgery. Capsular contracture is one of the most significant complications. Contraction of the wall of scar tissue surrounding the breast implant may cause hardness of the breast, discomfort and even severe pain. According to Health Canada, capsular contracture occurs, usually within two years of surgery, in approximately 25% of women who undergo breast implant surgery. Other researchers suggest the percentage is as high as 70%, and some estimate that 100% of women with breast implants will develop capsular contracture to some degree over the life of the implant.

Implant deflation and rupture caused by normal deterioration over time, breast trauma, undetected damage or shell weakness in the implant are significant complications; one study found that 70% of removed implants 11 to 15 years old were ruptured or leaking. In a U.S. government study, 2/3rds of 344 implanted women examined with MRI had ruptured implants. Deflation, leakage and rupture can result in the breast implant filling being spread through the body. The salt-water solution contained within saline-filled implants should be harmless. However, partly because of the semi-porous nature of breast implant shells and partly because of faulty valves and difficulties inherent in the sterilization of breast implant materials, it has been suggested that the saline filler does not remain sterile. In one study, most explanted saline-filled breast implants, regardless of their age, had microbial growth in the implant and in the capsule surrounding the implant. If the filler was so contaminated, it would no longer be considered harmless upon deflation or rupture.

Other complications include change in shape or volume of the breast; change in breast sensation; calcium deposits; mammographic interference, and breast/chest discomfort or pain and nipple discharge.

3. Systemic complications

Systemic complications appear most frequently several years after breast implantation. These complications tend to present as a cluster of symptoms, including those associated with autoimmune diseases, connective tissue diseases, “human adjuvant disease” and/or fibrositis/fibromyalgia-like disorders. (The classic autoimmune and connective tissue diseases thought to be associated with silicone implants are scleroderma, systemic lupus erythematosus, mixed connective tissue disease, rheumatoid arthritis and Sjogren-Larsson syndrome.) Women with breast implants have also reported granulomas and lymph node involvement, chronic flu, respiratory problems and infections. The cluster of symptoms reported by these women often includes those present in more than one such disease. Cancer also remains a concern – albeit a smaller one – associated with breast implants.

The link between breast implants and systemic complications is still not clearly understood. However epidemiologic research has not shown a significant increased risk.

4. Psychological complications

Unfortunately, studies of the psychological consequences of breast augmentation have been largely anecdotal, consisting primarily of surgeons’ reports of their patients’ satisfaction. These reports suggest that typically 70% or more of patients report satisfaction with their surgical outcome. However, such investigations clearly have serious problems. Firstly, how many patients will admit, face-to-face with their surgeon, that they are not satisfied with the results of their surgery? Secondly, how many surgeons will admit, face-to-face with their colleagues, that their patients are not satisfied?

There are many studies that suggest cosmetic surgery in general leads to immediate post-operative improvements in body image, quality of life and depressive symptoms. Other studies, however, have found that women who undergo removal of breast implants (explantation) report higher levels of breast anxiety, upper torso dissatisfaction and depression both before and after implant removal, compared to women who have undergone other cosmetic surgery (surgical controls) and women who have not undergone any cosmetic surgery (non-surgical controls). These findings suggest that breast implant surgery leads to poorer psychological well-being, rather than better, for many women.

Policy Issues

In Canada the only breast implants now widely available are saline-filled implants (a silicone bag filled with salt water). These implants, however, have not been reviewed by Health Canada.

The Medical Devices Regulations were introduced in Canada in 1975. These required notification of devices within 10 days of being put on the market, but involved no evaluation. These regulations were amended in 1977 so that evidence of safety and effectiveness was required before marketing. The list of

devices covered by this amendment did not, however, include breast implants. In October 1982, a further change to the regulations was implemented, which extended the pre-marketing review to all devices, including breast implants, designed to be implanted in tissues or bodies for more than 30 days.

The 1982 amendment required all implantable devices to go through a premarket evaluation of safety and effectiveness data in order to obtain a Notice of Compliance and be allowed for sale in Canada. This evaluation included a review by scientists at Health and Welfare Canada's Bureau of Radiation and Medical Devices of animal and human test results and manufacturing data supplied by the manufacturer. However, the review was required only for devices introduced after the date the amendment became effective. Because most saline-filled implants were available for sale before this date, they were exempted from the pre-market review.

Currently, despite the moratorium on silicone gel-filled breast implants, Health Canada has begun allowing their use in certain circumstances. There are suggestions that their popularity is again growing. Even as these silicone gel-filled implants are being reintroduced, there has still been little evaluation of the effects of the saline-filled implants that are currently widely available. This represents a gap in public policy and should be addressed by Health Canada.

4. LEVEL 3: RETROSPECTIVE CASE CONTROL

The impact of obesity on breast surgery complications, Chen, C L., Plast Reconstr Surg. 2011 Nov;128(5):395e-402e.doi: 10.1097/PRS.0b013e3182284c05.

ABSTRACT

Background: The increasing prevalence of obesity may worsen surgical outcomes and confound standardized metrics of surgical quality. Despite anecdotal evidence, the increased risk of complications in obese patients is not accounted for in these metrics. To better understand the impact of obesity on surgical complications, the authors designed a study to measure complication rates in obese patients presenting for a set of elective breast procedures.

Methods: Using claims data from seven Blue Cross and Blue Shield plans, the authors identified a cohort of obese patients and a nonobese control group who underwent elective breast procedures covered by insurance between 2002 and 2006. The authors compared the proportion of patients in each group who experienced a surgical complication. Using multivariate logistic regression, the authors calculated the odds of developing a surgical complication when obesity was present.

Results: There were 2403 patients in the obese group (breast reduction, 80.7 percent; reconstruction, 10.3 percent; mastopexy with augmentation, 1.5 percent; mastopexy alone, 3.5 percent; and augmentation alone, 4.0 percent). The occurrence of complications was compared for each procedure to a nonobese control group of 5597 patients. Overall, 18.3 percent of obese patients had a claim for a complication, compared with only 2.2 percent in the control group ($p<0.001$). Obesity status increased the odds of experiencing a complication by 11.8-fold after adjusting for other variables.

Conclusions: Obesity is associated with a nearly 12-fold increased odds of a postoperative complication after elective breast procedures. As quality measures are increasingly applied to surgical evaluation and reimbursement, appropriate risk adjustment to account for the effect of obesity on outcomes will be essential.

5. LEVEL 3: CASE-CONTROL

Factors Associated with Readmission following Plastic Surgery: A Review of 10,669 Procedures from the 2011 American College of Surgeons National Surgical Quality Improvement Program Data Set, *Plast. Reconstr. Surg.* 132: 666, 2013.

Background: This study explored factors associated with readmission following plastic surgery using a prospective, validated, national database.

Methods: Patients who underwent primary plastic surgery procedures (*n* = 10,669) were identified from the 2011 American College of Surgeons National Surgical Quality Improvement Program databases. Those who were readmitted were compared with those who were not. Preoperative patient comorbidities, laboratory values, and intraoperative details derived from the data set were analyzed, and multivariate regression analysis was used to identify predictors of readmission.

Results: A total of 10,669 patients were included, with a 4.5 percent readmission rate. Their average age was 49.5 years, 32.2 percent were obese, 15.2 percent were smokers, and 81.7 percent were women. The most commonly performed procedures included elective/cosmetic breast (23.4 percent), implant breast reconstruction (16.5 percent), revision breast procedures (14.9 percent), hand operations (9.7 percent), and body contouring (5.9 percent). The wound complication rate was 4.6 percent and the medical complication rate was 4.9 percent. The overall incidence of any postoperative complication was 10.9 percent, of which 4.8 percent were defined as major surgical complications. Independent risk factors associated with readmission included procedure type ($p = 0.029$); obesity ($p = 0.011$); anemia ($p = 0.003$); and medical ($p < 0.001$), major surgical ($p < 0.001$), and wound ($p < 0.001$) complications.

Conclusions: The most significant predictor of readmission was postoperative complications. Patients experiencing postoperative surgical complications were six times more likely to be readmitted. These findings can assist surgeons and health systems to better tailor preoperative risk counseling, resource allocation, and postoperative discharge services. (*Plast. Reconstr. Surg.* 132: 666, 2013.)

6. LEVEL 4: OBSERVATIONAL STUDY

Gynecomastia: Pathophysiology, Evaluation, and Management, *Mayo Clin Proc.* 2009;84(11):1010-1015

Concise Review for Clinicians

Ruth E. Johnson, MD, and M. Hassan Murad, MD, MPH Gynecomastia, defined as benign proliferation of male breast glandular tissue, is usually caused by increased estrogen activity, decreased testosterone activity, or the use of numerous medications. Although a fairly common presentation in the primary care setting and mostly of benign etiology, it can cause patients considerable anxiety. The initial step is to rule out pseudogynecomastia by careful history taking and physical examination. A stepwise approach that includes imaging and laboratory testing to exclude neoplasms and endocrinopathies may facilitate costeffective diagnosis. If results of all studies are normal, idiopathic gynecomastia is diagnosed. The evidence in this area is mainly of observational nature and lower quality.

From the Division of Preventive, Occupational and Aerospace Medicine, Mayo Clinic, Rochester, MN.

7. LEVEL 1: REVIEW

Breast Reduction Surgery for Hypermastia: Clinical Effectiveness and Guidelines, Rapid Response Report: Summary of Abstracts, Canadian Agency for Drugs and Technologies in Health, 21st August 2014

Review question:

1. What is the evidence that hypermastia causes neck, shoulder, or upper back pain in adult women?

2. What are the guidelines associated with breast reduction surgery in women?

Methods: A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 8), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were used to limit retrieval by publication type for question 1. A methodological filter was applied to limit retrieval to guidelines for question 2. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and August 12, 2014.

The summary of findings was prepared from the abstracts of the relevant information.

Evidence identified: One systematic review, three non-randomized studies, and three evidence-based guidelines regarding breast reduction surgery for hypermastia were identified.

Summary of findings: The identified systematic review found that women who underwent breast reduction surgery had improved outcomes regarding musculoskeletal pain, breathing, sleep, and headaches. One non-randomized study found that women who had larger breast tissue resection volumes had more often experienced pre-operative back pain, breast pain, shoulder grooves, rashes under the breasts, poor posture, and exercise intolerance than those who went on to have smaller resections; however, symptoms improved in both groups postoperatively. All data in this retrospective cohort study were collected retrospectively, therefore the results may be affected by recall bias. The

authors concluded that breast reduction surgery improved a variety of symptoms, regardless of body surface-area calculated adjustments and breast tissue resection volume. The remaining two non-randomized studies also found a postoperative improvement in breast-related symptoms, including quality of life, frequency of pain, and low-back compressive forces. These were small cohort studies, one using data from 59 patients, and the other 11 patients only.

One guideline suggests that breast reduction should be considered when resection weight is 500 grams or more, and that surgery is not to be considered in patients with a body mass index greater than 27.5. Two guidelines from the American Society of Plastic Surgeons state that resection volume is unrelated to symptom relief, and there is inconclusive evidence regarding the risk of complication associated with body mass index; ability to undergo surgery, and resection volume, should be at the discretion of the surgeon.

The guidelines suggest breast reduction surgery be considered for patients experiencing the following symptoms:

- back pain (upper or unspecified), neck pain and shoulder pain
- intertrigo, especially if unresponsive to medical intervention
- shoulder grooving from bra straps
- socially or emotionally bothered by large breasts
- physical activity limited by breast size
- breasts are low hanging, with stretched skin and enlarged areolas
- when breasts are unsupported, nipples hang below the breast crease
- acquired thoracic kyphosis
- chronic breast pain
- headache
- paresthesia of the upper extremities
- and congenital breast deformity

8. LEVEL 2: RANDOMISED CONTROLLED TRIAL

Risk Factors for Complications Following Breast Reduction: Results from a Randomized Control Trial, Srinivasaiah, N. et al. 2014, The Breast Journal, Volume 20 Number 3, 274–278

Purpose: To determine the effects of resection weight, BMI, age, and smoking on complication rates following reduction mammoplasty.

Methods: Data were gathered as a part of randomized control trial (RCT) examining psychosocial and Quality of Life benefits of reduction mammoplasty. Sixty-seven consecutive female patients referred to either the Hull Breast Unit or Hull Plastic and Reconstructive Surgery Unit and underwent inferior pedicle reduction mammoplasty were recruited. Complications were recorded prospectively. Data gathered included resection weight, BMI, age, and smoking status. Smoking

status was categorized into current; ex; and never. Prospective records of all complications were noted.

Results: Of the 67 patients, 16 (23.9%) had complications. Higher resection weight, increased BMI, and older age are associated with high rate of complications with significance reaching p-values of $p < 0.001$, $p = 0.034$, and $p = 0.004$, respectively.

Among the 67 women who had surgery, nine (13.4%) were current smokers, 20 (29.9%) were ex-smokers, and 38 (56.7%) never smoked. The incidence of complications was highest among current smokers and lowest among those who had never smoked. When comparing the current smokers with those who are not currently smoking, there is a 37% difference in the occurrence of complication. The chi-squared test shows that this is a significant difference ($p < 0.01$) at the 99% confidence interval.

Conclusions: Higher resection weight, increased BMI, older age, and smoking are risk factors for complications.

9. LEVEL 3: RETROSPECTIVE COHORT STUDY

An Outcomes Analysis of 2142 Breast Reduction Procedures, Manahan, M.A. et al 2015, Annals of Plastic Surgery, Volume 74 No.3, 289 – 292

ABSTRACT

Background: This study investigated a large series of consecutive breast reductions to study important factors that impact outcomes.

Methods: A retrospective review of all breast reductions from 1999 to 2009 in a single institution (John Hopkins Medical Institutions in USA) was performed using the medical record for demographics, medical history, physical examination, intraoperative data, and postoperative complications. Multivariate statistical analysis was performed. $P \leq 0.05$ defined significance.

Results: Seventeen surgeons performed 2152 consecutive breast reductions on 1148 patients using inferior pedicle/Wise pattern (56.4%), medial pedicle/Wise pattern (16.8%), superior pedicle/nipple graft/Wise pattern (15.1%), superior pedicle/vertical pattern (11.6%), and liposuction (0.1%) techniques. 90.5% of breast reductions were performed to address symptomatic macromastia (n = 1947). The remainder were performed to match a breast reconstruction or partial mastectomy. 2% were a secondary procedure after prior reduction.

Complications included discernible scars (14.5%), nonsurgical wounds (13.5%), fat necrosis (8.2%), infection (7.3%), wounds requiring negative pressure wound therapy or reoperation (1.4%), and seroma (1.2%). Reoperation rates were 6.7% for scars, 1.4% for fat necrosis, and 1% for wounds.

Body mass index greater than or equal to 35 kg/m increased risk of infections [odds ratio (OR), 2.3, P = 0.000], seromas (OR, 2.9, P = 0.03), fat necrosis (OR, 2.0, P = 0.002), and minor wounds (OR, 1.7, P = 0.001). Cardiac disease increased reoperation for scar (OR, 3.0, P = 0.04) and fat necrosis (OR, 5.3, P = 0.03). Tobacco use increased infection rate (OR, 2.1, P = 0.008). Secondary surgery increased seromas (OR, 12.0, P = 0.001). Previous hysterectomy/oophorectomy increased risk of wound reoperations (OR, 3.4, P = 0.02), and exogenous hormone supplementation trended toward decreasing infections (OR, 0.5, P = 0.08). χ analysis revealed 7.8% infection risk without exogenous hormone versus 3.8% risk with hormone supplementation (P = 0.02).

None of the breast reduction techniques was found to be independently responsible for an increase in any of the evaluated complications. Size of reduction was also not found to significantly contribute to complication profiles.

Conclusions: Morbid obesity, tobacco, cardiac history, and secondary surgery negatively impacted breast reduction outcomes. Hormonal status impacted reoperations and infections.

10. LEVEL 3: RETROSPECTIVE COHORT STUDY

Risk factors for complications after breast reduction surgery, Lewis R. et al 2014, Journal of Plastic Surgery & Hand Surgery, Volume 48, 10-14

ABSTRACT

Background: Women who suffer from breast hypertrophy commonly have physical symptoms such as back pain and psychosocial problems. Breast reduction surgery is performed to relieve these problems. Side-effects must be kept to a minimum. Risk factors for developing postoperative complications have not clearly been identified so far. The aim of this study was to identify risk factors that lead to complications.

Method: The medical records of 512 consecutive women (mean age 40 years) who underwent bilateral breast reduction between January 2001 and December 2007, at the Department of Plastic Surgery, Sahlgrenska University Hospital in Sweden, were retrospectively studied. Complications that occurred during the first 30 days after the operation were retrieved from medical records. Complications that the study explored were infection, delayed wound healing, fat necrosis and areola necrosis.

Results: Complications occurred in 32% of the patients within 30 days of surgery. The most common complication was infection at the surgical site (16%) followed by delayed wound healing (10%). Fat necrosis occurred in 2.5%, partial areola necrosis in 3.1%, and total areola necrosis in 0.6% of the patients. A longer suprasternal notch to nipple distance gave significantly higher risk of postoperative infection ($p < 0.001$) and necrosis in the mammilla ($p < 0.001$). The resected specimen weight during the operation was found to significantly influence the risk of delayed wound healing ($p = 0.021$) and fat necrosis ($p < 0.001$). Smokers had twice the risk of getting a postoperative infection, RR = 2.0 (95% CI = 1.3-3.1). Diabetics had a significantly higher risk of necrosis of the areola ($p = 0.003$). All the above predictors were identified as independent predictors.

Conclusion: Complications after breast reduction are common. The study has identified several risk factors for complications, some of them independent, which might be avoidable by performing a careful preoperative evaluation of the patient.

11. LEVEL 4: CASE SERIES

Inverted nipple repair revisited: a 7-year experience, Gould D.J. et al 2015, Aesthetic Surgery Journal, Volume 35, No. 2, 156-164

ABSTRACT

Background: Nipple inversion in females can be congenital or acquired. Women who desire treatment for this condition often report difficulty with breastfeeding and interference with their sexuality. However, data are limited on the demographics of patients who undergo surgery to repair inverted nipples and the associated recurrence rates and complications.

The authors assessed outcomes of a 7-year experience with an integrated approach to the correction of nipple inversion that minimizes ductal disruption.

Methods: A retrospective chart review was performed for 103 consecutive patients who underwent correction of nipple inversion. Complication rates, breastfeeding status, and patient demographics were documented.

Results: Among the 103 patients, 191 nipple corrections were performed. Nine patients had undergone previous nipple-correction surgery. Recurrence was experienced by 12.6% of patients, 3 of whom had bilateral recurrence. Other complications were partial nipple necrosis (1.05%), breast cellulitis (1.57%), and delayed healing (0.5%). The overall complication rate was 15.74%. Fifty-seven percent of the patients had a B-cup breast size, and 59% were 21 to 30 years of age.

Conclusions: The authors conclude that this study demonstrates the safety and effectiveness of their technique to correct inverted nipples.

Appendix 2 – Measuring Bra Size

Aesthetic Breast Surgery
GM006-GM010

Method 1: To be used for breast asymmetry

- The bra size is determined by both a band size (e.g. 36) and a cup size (e.g. C) to come up with the bra size (e.g. 36C).
- Measure the size while the individual is wearing an unlined or thinly lined bra.
- Measure band size:
  - Using a soft measuring tape, measure around the rib cage in inches, just beneath the bust. Ensure that the tape is snug, smooth, and level in the front and back.
  - Discard any fraction (e.g. if the measurement is 31.5 inches, consider 31 inches). Add 5 inches to the measurement if the ribcage is odd and 4 inches if it is an even number (in our example, the band size is 36 inches).
  - Fuller figured women with rib cage measurements of more than 36 inches may need to add either 1 or 3 inches to get to the next even numbered band size.
- Measure cup size:
  - Measure across the fullest part of each breast (across the nipple), starting at the outside of the breast crease and going to the inside of the crease.
  - A cup size is allocated to each measurement:
    - 7 inches = A cup
    - 8 inches = B cup
    - 9 inches = C cup
    - 10 inches = D cup
    - 11 inches = DD cup
    - 12 inches = E cup
    - 13 inches = F cup
    - 14 inches = FF cup
    - 15 inches = G cup
- It should be noted that this cup size measurement seems most accurate for women with band sizes in the 34 and 36 range.
- Because manufacturers make cup sizes smaller for smaller band sizes, and larger for larger band sizes, women with a 30-32 inch band measurement should deduct about 1 inch from these measurements (A cup = 6 inches, B cup = 7 inches and so on). Women in the 38-40 inch band size range will find that bras are upsized in cup size at these band measurements (women in this size range are more likely to be an A cup at 8 inches, B cup at 9 inches and so on).

Method 2

- Alternatively, a more traditional way of measuring cup size is keeping the measuring tape straight and snug, measure around the fullest part of the bust. Subtract the rib cage measurement from this measurement.
- The difference is the basis for the cup size; each inch of difference is equal to one cup size:
  - less than 1 inch difference = AA cup
  - 1 inch difference = A cup
  - 2 inch difference = B Cup
  - 3 inch difference = C Cup
  - 4 inch difference = D Cup
  - 5 inch difference = DD Cup
  - 6 inch difference = E Cup
  - 7 inch difference = F Cup
  - 8 inch difference = FF Cup
  - 9 inch difference = G Cup

Policy guidance from NHS England Interim Clinical Commissioning Policy:
Breast Asymmetry Correction Surgery (November 2013)

List of band and cup sizes in ascending order of size

NOTE:

- Most double cup sizes are one size up from the single letter, with the exception of AA which is smaller than an A cup.
- When assessing for asymmetry there should be a minimum of 2 cup sizes between the sizes given for each breast.

28AA	30AA	32AA	34AA	36AA	38AA	40AA	42AA	44AA
28A	30A	32A	34A	36A	38A	40A	42A	44A
28B	30B	32B	34B	36B	38B	40B	42B	44B
28C	30C	32C	34C	36C	38C	40C	42C	44C
28D	30D	32D	34D	36D	38D	40D	42D	44D
28DD	30DD	32DD	34DD	36DD	38DD	40DD	42DD	44DD
28E	30E	32E	34E	36E	38E	40E	42E	44E
28F	30F	32F	34F	36F	38F	40F	42F	44F
28FF	28FF	32FF	34FF	36FF	38FF	40FF	42FF	44FF
28G	30G	32G	34G	36G	38G	40G	42G	44G
28GG	30GG	32GG	34GG	36GG	38GG	40GG	42GG	44GG
28H	30H	32H	34H	36H	38H	40H	42H	44H
28HH	30HH	32HH	34HH	36HH	38HH	40HH	42HH	44HH
28J	30I	32I	34I	36I	38I	40I	42I	44I
28JJ	30J	32J	34J	36J	38J	40J	42J	44J
28JJ	30JJ	32JJ	34JJ	36JJ	38JJ	40JJ	42JJ	44JJ
28K	30K	32K	34K	36K	38K	40K	42K	44K
	30KK	32KK	34KK	36KK	38KK	40KK	42KK	44KK
		32L	34L	36L	38L	40L	42L	44L

Appendix 3 – Diagnostic and Procedure Codes

Aesthetic Breast Surgery
GM006-GM010

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

GM006-GM010 - Aesthetic Breast Policy	
Augmentation (breast enlargement)	
Augmentation mammoplasty	B31.2
With the following ICD-10 diagnosis code(s):	
Other plastic surgery for unacceptable cosmetic appearance	Z41.1
Exceptions (ICD-10):	
Congenital absence of breast with absent nipple	Q83.0
Absent nipple	Q83.2
Other congenital malformations of breast	Q83.8
Revision of breast augmentation	
Revision of prosthesis of breast	B30.2
Removal of prosthesis of breast	B30.3
Renewal of prosthesis of breast	B30.4
Revision of mammoplasty; plus,	B31.4
Removal of prosthesis from organ NOC; or	Y03.7
Renewal of prosthesis in organ NOC; or	Y03.2
Correction of displacement of prosthesis NOC	Y03.3
Lipofilling of breast	B37.5
With the following ICD-10 diagnosis code(s):	
Other plastic surgery for unacceptable cosmetic appearance	Z41.1
Exceptions (ICD-10):	
Mechanical complication of breast prosthesis and implant	T85.4
Mastopexy (breast lift)	
Mastopexy	B31.3
Revision of mammoplasty (not specific to 'revision of mastopexy')	B31.4
With the following ICD-10 diagnosis code(s):	
Other plastic surgery for unacceptable cosmetic appearance	Z41.1
Exceptions (OPCS-4); when associated with:	

Reduction mammoplasty	B31.1
Reduction mammoplasty (Female breast reduction)	
Reduction mammoplasty	B31.1
With the following ICD-10 diagnosis code(s):	
Hypertrophy of breast	N62.X
Gynaecomastia (male breast reduction)	
Reduction mammoplasty	B31.1
With the following ICD-10 diagnosis code(s):	
Hypertrophy of breast	N62.X
Surgical correction of nipple inversion	
Eversion of nipple	B35.6
With the following ICD-10 diagnosis code(s):	
Other signs and symptoms in breast; or	N64.5
Other congenital malformations of breast	Q83.8

Appendix 4 – Version History

Aesthetic Breast Surgery
GM006-GM010

The latest version of this policy can be found here: GM Aesthetic Breast Surgery Policy

Version	Date	Summary of Changes
0.1	09/09/2013	Initial Draft for consideration by GM EUR Steering Group.
0.2	19/09/2013	Inclusion of criteria following discussion at the GM EUR Steering Group meeting on 18/09/2013.
0.3	09/10/2013	Inclusion of criteria to confirm patient has worn a professionally fitted bra.
0.4	15/10/2013	• First paragraph in Commissioning Recommendation reworded to match statement in rest of policy. • Policy Summary moved to Introduction in line with template. • Paragraph on "Revision of Breast Augmentation" reworded. • Evidence summary changed to match summary on Appendix 1 – Evidence Review • Absence of Evidence Summary added. • Mechanism for Funding paragraph reworded in line with template. • Inclusion of Appendix 1 – Evidence Review • Formatted.
0.5	15/01/2014	Feedback from the consultation considered by the GM EUR Steering Group. 25 people responded to the consultation. Amendment of the policy to include the insertion of a paragraph regarding breast augmentation for male to female gender realignment and mastectomy procedures for female to male gender realignment.
1.0	11/03/2014 01/04/2014	Approved at Greater Manchester Heads of Commissioning and Greater Manchester Chief Finance Officers Approved at Greater Manchester Association Governing Group
1.1	May 2015	Policy reviewed and moved to NWCSU template.
2.0	25/06/2015	Changes made following annual review by GM EUR Steering Group on 20 May 2015: • Review date added - May 2015 • Wording in Date of Review box amended to read *'One year from the date of approval by Greater Manchester Association Governing Group and annually thereafter.'* • Surgical correction of nipple inversion added to commissioning recommendation. • Inverted nipple correction added to the procedures requested included list. • Under Breast Asymmetry the following sentence added *'For the purposes of this policy asymmetry is defined as a difference of 3 or more cup sizes.'* • Definition of nipple inversion added. • Section 4 - Criteria for Commissioning - Following sentence added under Mandatory Criteria *'For all applications relating to the female breast, measurements should be submitted using the measuring guide in appendix 2 of this policy.'* • And the following paragraph added under Revision of Breast Augmentation: *'The Department of Health advice on Poly Implant Prothèse (PIP) implants*

		recommends that where woman who has PIP implants decides, with her doctor, that in her individual circumstances she wishes to have her implants removed, her healthcare provider should support her in carrying out this surgery. Where her original provider is unable or unwilling to help, the NHS will remove but not normally replace the implant.' • Under Breast Reduction bullet point 5 *'Proof of purchase'* has been removed. • Under Breast Asymmetry following added (e.g. C and E) & under the standard information required added: o Evidence of current height and weight, and that the weight has been stable for at least 2 years (BMI must be less than 30). o Patients must have completed puberty • Inverted Nipple Correction added under mandatory criteria • Section 6 - Evidence Summary updated • Section 8 - Adherence to NICE Guidance - NICE have not currently issued guidance on this treatment. • Appendix 1 - Evidence Review updated following review in May 2015 • Appendix 2 - Measuring Bra Size added
2.1	16/09/2015	For further clarification on the 16th September 2015 the Greater Manchester EUR Steering Group agreed the following changes to the policy: • <u>Revision of Breast Augmentation:</u> Sentence added to the second paragraph: *'To avoid creating asymmetry the non-faulty implant may be removed at the same time.'* • <u>Breast Reduction:</u> the 5PthP bullet point amended to read *'Confirmation that a correctly fitted bra has been worn for a period of at least 6 months and has not relieved the symptoms. Patients must provide evidence of an independent measurement of band size and cup size using either of the two methods for cup size as detailed in Appendix 2. <u>OR</u> a clinical measurement (e.g. sternal notch to nipple distance, breast volume).'* • <u>Breast Asymmetry:</u> amended to read as follows: *'Breast Asymmetry is commissioned where there is a difference in breast size of 3 cups (e.g. C and E) or more and the criteria listed below (in bullet point form) have been met. Clinicians can submit an Individual Funding Request (IFR) if they feel there is a good case for exceptionality. Due to the risks and long term implications relating to breast implants, surgery to reduce the larger breast only will be approved. Requests made by clinicians to enhance the smaller breast, will be considered under clinical exceptionality this includes but is not limited to cases where reduction to the size of the larger breast would leave the women with a bust size disproportionate to her frame.* • *A difference of 3 cup sizes or more evidenced by an independent measurement of band size and cup size using the using the first of the two methods outlined in Appendix 2 **<u>OR</u>** a clinical measurement (e.g. sternal notch to nipple distance, breast volume).* • *Evidence of current height and weight, and that the weight has been stable for at least 2 years (BMI must be less than 30).* • *Patients must have completed puberty.* *Non-identifiable photographs, preferably medical illustrations if available, will be requested, to support the decision making process, but will not form the sole basis of the decision. It is <u>not</u> mandatory for photographs to be provided by a patient.* *A statement of clinical exceptionality must be included if the patient does not meet the criteria above OR if an enlargement to the smaller breast is being requested.*

	18/11/2015	On the 18 November 2015 the GM EUR Steering Group approved the changes made to the policy on 16 September 2015 and agreed that these did result in a change to the commissioning of aesthetic breast surgery across Greater Manchester.
2.2	16/02/2016	• Section 2 - Definition: In the Amastia (and Amazia) paragraph the word *'Amazia'* corrected to read *'Amastia'*. • Section 4 - Commissioning Criteria: Under Breast Augmentation the final sentence of the second paragraph amended to read *'amazia'* not *'amastia'*. • Section 14 - Glossary: The meaning of amastia and amazia has been corrected.
2.3	05/04/2016	• List of diagnostic and procedure codes in relation to this policy added as Appendix 3. • Policy changed to Greater Manchester Shared Services template and references to North West Commissioning Support Unit changed to Greater Manchester Shared Services. • Date of Review and Policy Statement: Wording amended to read *'One year from the date of approval by Greater Manchester Association Governing Group thereafter at a date agreed by the Greater Manchester EUR Steering Group (unless stated this will be every 2 years)'*
2.4	14/12/2016	Appendix 3 - Mammoplasty (female breast reduction): the following diagnostic codes were removed from exceptions: • M54.2 - Cervicalgia • M54.5 - Low back pain • M54.9 - Dorsalgia, unspecified • L30.4 - Erythema intertrigo
3.0	17/05/2017	Following scheduled review at GM EUR Steering Group the following amendments were agreed, subject to a virtual final approval by the group once changes made: • Policy moved to new policy format • Commissioning Statement o *'Policy Exclusions'* section moved to the beginning of the *'Commissioning Statement'*. o *'Our definition of Aesthetic'* section added o Under every heading apart from *'Inverted Nipple Correction'*, the following statement added: *'All surgery involving incision into healthy tissue in this case a healthy breast whatever its size and shape is considered to be aesthetic.'* o Under *'Breast Augmentation'*, the following paragraph added to replace the original 1st paragraph: *'Surgery to augment the size and or shape of a breast(s) is not routinely commissioned, with the exception of proven amastia or amazia. There should be confirmation either in the form of a consultant letter or an ultrasound report that there is an absence of breast tissue.'* o The following note added to sections on *'Breast Augmentation'* and *'Revision of Breast Augmentation'*: *'NOTE: In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for ALL applications relating to the female breast, measurements must be submitted using either method in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. Applications using other methods will not be accepted.'* o Under *'Breast Reduction'*, the following statement added to the original

		2nd paragraph: *'Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality:'* and the first bullet point amended to read: *'In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for ALL applications relating to the female breast, measurements must be submitted using <u>either</u> method in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. Applications using other methods will not be accepted.'* o Under *'Gynaecomastia'*, the following statement added to the original 2nd paragraph: *'Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality:' and a section added around 'adolescent patients requesting surgery for gynaecomastia'.* o Under *'Breast Asymmetry'*, the original first paragraph replaced by: *'However surgery is commissioned where there is a difference in breast size of 3 cups (i.e there should be at least 2 cup sizes between the sizes given for each breast). For example: the difference between a B cup on one side and a DD on the other is 3 cup sizes with 2 cup sizes in between: B to (C to D) to DD.* *The following standard set of information will need to be provided in addition to the individual clinical exceptional circumstances. Please NOTE that these are not qualifying criteria, they provide a standard set of information which is used by panels as an aid when determining exceptionality:' and the first bullet point amended to read: 'Current band and cup measurements for both breasts. In order to ensure consistency in decision making and a full understanding of the clinical picture by all staff reviewing the case for ALL applications relating to the female breast, measurements must be submitted using <u>Method 1</u> in Appendix 2 of this policy, please give actual measurements as well as the band and cup size. Applications using other methods will not be accepted.'* • <u>Date of Review:</u> Section amended to include standard wording and that next review will be in two years. • <u>Appendix 1: Evidence Review:</u> Under *'Summary of the evidence'* the wording *'Last updated: May 2015'* was amended to read: *'The search was repeated for the scheduled policy reviews in May 2015 and April 2017.'* • <u>Appendix 2: Measuring Bra Size:</u> Titles added to distinguish the two different methods of measuring.
	16/06/2017	Following virtual final approval of the amendments made at the meeting on 17/05/2017, the following additional changes were made before publication of the reviewed policy: • <u>Commissioning Statement:</u> *'(See Appendix 2 for table of band and cup sizing)'* added to the end of paragraph 2 under *'Breast Asymmetry'*. • <u>Appendix 2: Measuring Bra Size:</u> Breast table merged into one with notes on double cup sizing and the minimum difference in cup size required for asymmetry.
3.1	19/07/2017	<u>Breast Reduction:</u> Bullet point that reads: *'Patients <u>must</u> have completed their families'* amended to: *'Patients must be advised that if they go on to have further children they may develop further problems and it is unlikely that further surgery would be funded on the NHS.'* at the request of the GM EUR Steering Group.
3.2	20/09/2017	<u>Breast Reduction:</u> Bullet point *'Patients must be advised that if they go on to have further children they may develop further problems and it is unlikely that further surgery would be funded on the NHS.'* amended to: *'Patients must be advised that if they go on to have further children they may develop further*

		aesthetic problems with the breasts and it is unlikely that further aesthetic breast surgery would be funded on the NHS.' at the request of the GM EUR Steering Group.
3.3	17/01/2018	At the request of the GM EUR Steering Group, the following amendments were made: <u>Commissioning Statement</u> • Section for *'Fitness for Surgery'* added. • Bullet point added to state *'The patient must have completed puberty'* added to all relevant sections where it was not stated, for consistency. • Statement to read *'If applying for funding on the grounds of clinical exceptionality the following standard set of information will need to be provided in addition to the individual clinical exceptional circumstances.'* added or added to existing wording on all relevant sections where a standard set of information is required for determining exceptionality. • All statements on height weight and BMI amended for consistency. • Bullet points added to 'Breast Asymmetry' criteria for breast measurement, puberty and BMI, for consistency, and bullet point added to *'Note'* regarding surgery being affected by weight. • Gynaecomastia split into two headings for 'Adult' and 'Adolescent'. • Adolescent Gynaecomastia: *'Note'* on puberty bullet point added.
3.4	06/06/2018	Appendix 3: OPCS-4 procedure code B37.5 Lipofilling added
3.5	23/01/2019	• Branding changed to reflect change of service from Greater Manchester Shared Services to Greater Manchester Health and Care Commissioning. • Links updated as documents have all moved to a new EUR web address • <u>Commissioning Statement:</u> o *'(Alternative commissioning arrangements apply)'* added after Policy Exclusions o *'Fitness for Surgery'* section moved to bottom of *'Commissioning Statement'* o *'Best Practice Guideline'* section added