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Arbenigol Cymru (PGIAC)
Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Policy: CP69 Breast Surgery Procedures

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Document History

Revision History			
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		This policy replaces sections 5.1 Breast Procedures in CP39 – Plastic Surgery Commissioning Policy	
0.1	09/11/12	Two minor technical amendments were proposed	0.2
1.0	04/03/13	Algorithm for Referral for Procedure added: Minor amendment on responsibilities: Annex (iii) added Referral forms	1.1
1.1	05/03/2013	Ratified through Chair's Action on behalf of Management Group	2.0
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Consultation		
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Plastic Surgery Oversight Group	09/11/12	0.1

Approvals		
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Management Group Meeting	13/12/12	1.0
WHSSC Management Group	05.03.2013	2.0

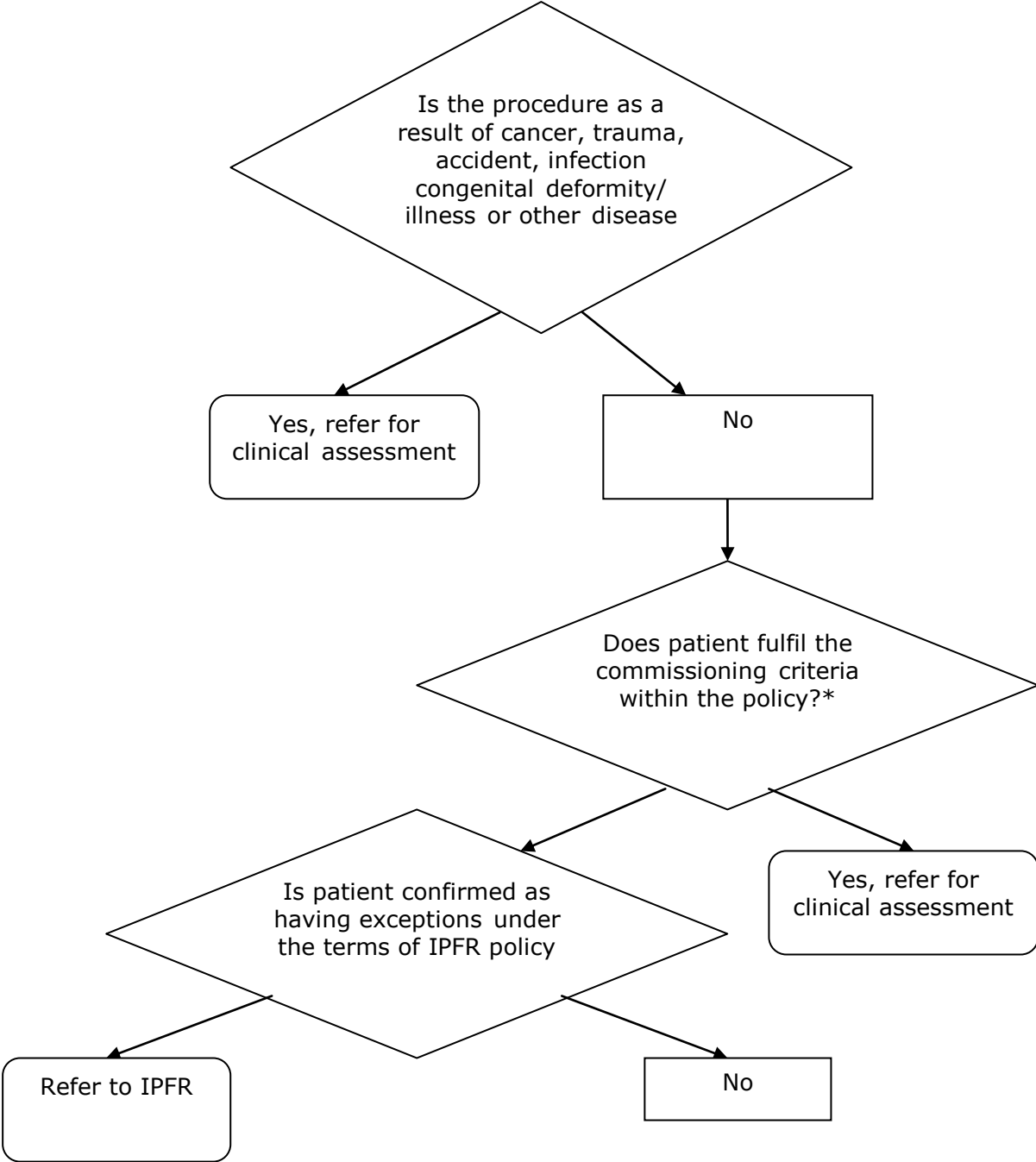
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Health Board, Directors of Planning	Specialised Planner	01/03/13	1.0
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Policy Statement

<p>Background</p>	<p>Reconstructive breast surgery is undertaken to reshape abnormalities arising from cancer, accidents, injuries, infections, and other diseases as well as congenital deformity. Treatment for these conditions is available on the NHS and the access criteria specified in this policy does not apply to referrals for these conditions.</p> <p>It is recognised that in addition to the conditions listed above there are circumstances where access to breast surgery is appropriate and should be available to NHS patients e.g. for medically necessary treatment where there is significant pain or discomfort which affects daily activities and is not amenable to routine treatment.</p> <p>Breast surgery undertaken with the sole purpose of cosmetic improvement will not be routinely funded by NHS Wales.</p>
<p>Statement</p>	<p>This policy is written in recognition of the service agreements which exist for the provision of breast surgery and describes the eligibility criteria for these procedures.</p> <p>Patients may satisfy the criteria or may be confirmed as exceptions under the terms of the All Wales Individual Patient Funding Request (IPFR) policy.</p>
<p>Responsibilities</p>	<p>Referrers are responsible for providing the clinical detail required on the appropriate referral form, copies of these can be found in annex (iii). The pro forma is there to ensure all the relevant clinical detail required to assess the patients eligibility for out- patient assessment and surgery is provided. Any referrals not on these will be returned to the referrer.</p> <p>Managers are responsible for ensuring that all relevant staff are aware of NHS Wales policies and adhere to them.</p> <p>Managers are responsible for ensuring that systems are in place for their areas of responsibility to enable staff to keep up to date with new policy</p>

	<p>changes.</p> <p>NHS Wales staff are responsible for ensuring that they are familiar with policies pertaining to their area of work, know where to locate the documents and seek out every opportunity to keep up to date with NHS Wales policies.</p> <p>Independent contractors are expected to identify a lead individual to be responsible for ensuring that all staff employed within their practice are aware of and adhere to NHS Wales policies.</p>
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Algorithm for Referral for Procedure



*All requests for patients who require assessment of eligibility through application of the commissioning criteria will need to be made on the relevant pro formas, annex ii-iv of this policy.

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1. Aim

1.1 Introduction

This document has been developed as the policy for the planning of Breast Surgery procedures which are not connected with accident, injury, infection, cancer, other diseases or congenital deformity for Welsh patients.

The purpose of this document is to:

- clearly set out the circumstances under which patients will be able to access treatment;
- clarify the referral process;
- define the criteria that patients must meet in order to be referred.

Breast surgery procedures with the sole purpose of improving cosmetic appearance are not routinely funded by NHS Wales.

1.2 Relationship with other Policy and Service Specifications.

This document should be read in conjunction with the following documents:

- Commissioning policy for access criteria and service specification for specialised Gender Identity Services CP21.
- All Wales Individual Patient Funding Request policy.

2. Scope

2.1 Definition

Reconstructive breast surgery is undertaken to reshape abnormalities arising from cancer and other diseases, accidents, injuries, infections as well as congenital deformity.

In addition there are circumstances where access to breast surgery is appropriate and should be available to NHS patients e.g. for medically necessary treatment where there is significant pain or discomfort which affects daily activities and is not amenable to routine treatment.

2.2 Criteria for eligibility:

Circumstances in which breast surgery procedures may be funded by NHS Wales:

- Procedures to reshape abnormalities arising from cancer, accidents, injuries, infections or other diseases as well as congenital deformity are routinely funded;
- Procedures undertaken with the aim of improving the function of a body part;
- Procedures which are medically necessary and where conservative treatment options have been exhausted.

This policy provides clarification regarding the access criteria agreed by NHS Wales for breast surgery procedures. It represents the current commissioning priorities in NHS Wales and aims to provide clarification to GPs, specialist clinicians, service providers and patients alike.

2.3 Codes

Procedure	ICD10	OPCS4
Augmentation/mammoplasty (breast enlargement)		B301, B302, B304, B308, B309, B312, B314, B375
Gynaecomastia	N62	B311, B275
Mastopexy		B313
Reduction mammoplasty	N62, N648, Q838, Q839, Z411, Z421	B311
Revision of augmentation/mammoplasty	T859, T854, T857, Z411, Z421	B314, B302
Surgical correction of nipple inversion	Q838, O920, Z42	B356
Mastectomy (Associated with Gender Reassignment Surgery)		B27

3. Access Criteria

3.1 Clinical Indications

3.1.1 Patients should be at least 18 years of age.

3.1.2 NHS Wales will not routinely fund breast procedures unless:

- Treatment is required to reshape abnormalities arising from cancer, accidents, injuries, infections and other diseases or congenital deformity;
AND/OR
- Treatment is deemed medically necessary and conservative treatment options have been exhausted;
AND/OR
- There is evidence of significant impaired ability to perform activities of daily living which has been formally assessed.

3.1.3 Psychological distress alone will normally not be accepted as a reason to fund surgery. Applications which cite psychological distress will need to be evidenced with a current psychological assessment which specifically addresses the cause for the application.

In exceptional circumstances psychological distress alone will be considered as a reason for aesthetic surgery if it may alleviate severe and enduring psychological dysfunction. In these cases an NHS psychiatrist or psychologist must provide demonstrable evidence of treatment(s) used to alleviate /improve the patient's psychological well being, including the impact and duration of treatment(s). Patients should be currently engaged or have undergone appropriate psychological or psychiatric treatment. Patients should NOT be referred to mental health services specifically to support a referral for aesthetic surgery.

Clinicians are asked to refer to NICE guideline 31 on Obsessive Compulsive Disorder (OCD) and Body Dysmorphic Disorder (BDS) prior to referring on psychological grounds alone.

The indicative criteria/guidelines for aesthetic breast surgery procedures are detailed in section 3.2 below.

3.2 Criteria for Treatment

3.2.1 Female breast reduction (reduction mammoplasty)

Requests for female breast reduction need to be made using the pro forma, annex(ii), to allow providers to assess the patients eligibility for surgery against the commissioning criteria. Any request not on the appropriate pro forma will not be considered and will be returned to the referrer.

Surgical intervention will be considered for patients experiencing enduring significant clinical symptoms which include:

At least **TWO** of the following for at least one year with documented evidence of GP visits in relation to these problems:

- Significant chronic pain in the neck
- Significant chronic pain in the upper back
- Significant chronic pain in the shoulders
- Painful kyphosis documented by x ray
- Skin problems including pain, discomfort and ulceration. Chronic intertrigo, eczema or dermatitis alone will not be considered as grounds for this procedure unless the patient has failed to respond to 6 months of conservative treatment.

Significant chronic pain symptoms persist as documented by the referring clinician despite a 6 month trial of therapeutic measures including **ALL** of the following (supporting evidence to be submitted with application):

- Supportive devices e.g. bra of the correct size with wide straps and fitted by a trained bra fitter;
- Analgesic/ NSAID interventions;
- A completed programme of physical therapy/exercises/posturing manoeuvres supervised by an appropriately trained therapist.

AND

Estimated reduction greater than 550 grams per breast on each side (American Medical Association guidelines, 2008)

AND

BMI < 25 Kg/M²

OR

Patients with virginal hyperplasia/hypertrophy OR patients with gross asymmetry (defined as a difference of > 2 standard cup sizes*) to the extent that it is not possible to get a bra which fits

*** Standard cup sizes – AA, A, B, C, D, DD, E, F, FF,G, GG, H, HH, J, JJ, K,L**

Requests for

3.2.2 Male breast reduction for gynaecomastia

Requests for male breast reduction need to be made using the pro forma, annex(iii), to allow providers to assess the patients eligibility for surgery against the commissioning criteria. Any request not on the appropriate pro forma will not be considered and will be returned to the referrer.

In cases of idiopathic gynaecomastia for men aged under 25 years of age a period of 2 years should be allowed for natural resolution as in general after other causes have been excluded conservative management is usually appropriate. Screening should be undertaken to eliminate endocrinological and drug related causes Failure of resolution after 2 years is a reasonable time after which conservative treatment is unlikely to be associated with natural resolution and surgery can be considered.

Surgical intervention will be considered for patients who fulfil the following criteria:

Grade III Gynaecomastia where resection would be >100 grams (avoids minor purely cosmetic requests).

OR

For specific un-correctable aetiological factors identified such as androgen therapy or caused by the side effects of treatment of another condition such as the side effect if treatment for prostate cancer.

AND

- Post pubertal with BMI in the range of i.e. 18 – 25 Kg/M² maintained for a period of 12 months.

3.2.3 Breast Enlargement (augmentation mammoplasty)

Requests for breast enlargement need to be made using the pro forma, annex(iv), to allow providers to assess the patients eligibility for surgery against the commissioning criteria. Any request not on the appropriate pro forma will not be considered and will be returned to the referrer.

Breast augmentation as a result of previous mastectomy and other excisional breast surgery, including revision to the other breast to correct asymmetry or reconstruction following trauma to the breast, are routinely provided and outside the scope of this policy.

In other circumstances breast augmentation may be provided on an exceptional basis. Augmentation will not be undertaken for 'small' but otherwise normal breasts.

Trans women requesting breast augmentation will need to fulfil the same criteria as born females.

Patients should have a BMI of 18 kg/m² -25 kg/m²

3.2.4 Revision of breast augmentation

Replacement of implants will be considered, for clinical reasons, if the original implants were funded by the NHS.

Removal of implants will be considered, but not replacement, if at least **ONE** of the following criteria are met:

- Rupture of silicone- filled gel;
- Implants complicated by recurrent infection;
- Extrusion of implant through skin;
- Implants with Baker Class IV contracture associated with severe pain;
- Implants with severe contracture which interferes with mammography.

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

3.2.5 Breast uplift (Mastopexy)

Mastopexy undertaken in isolation is not routinely funded by NHS Wales. Funding will only be considered if exceptional circumstances are demonstrated through an IPFR application.

3.2.6 Surgical correction of nipple inversion

This procedure is not routinely funded by NHS Wales and funding will only be considered if exceptional circumstances are demonstrated through an IPFR application.

3.2.7 Mastectomy associated with Gender Reassignment Surgery

Mastectomy is available for female to male trans patients who have been approved for NHS funded Gender Reassignment Surgery

3.3 Referral Pathway

Breast procedures are undertaken by specialities including plastic surgery, oncoplastic and general breast surgery. The access criteria specified in this policy should be applied to all referrals for breast procedures. Referrals for female breast reduction, gynaecomastia (male breast reduction), and breast augmentation should be made using the relevant pro forma. These can be found in annex ii-iv of this policy.

3.4 Exclusions

Referral under this policy does not include the following groups:

- Patients referred following cancer, accidents, injuries, infections, and other diseases as well as congenital deformity.

3.5 Exceptions

If the patient does not meet the criteria for treatment, but the referring clinician believes that there are exceptional grounds for treatment an Individual Patient Funding Request (IPFR) can be made to WHSS under the All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR).

If the patient wishes to be referred to a provider out of the agreed pathway, an IPFR should be submitted.

Guidance on the IPFR process is available at www.whssc.wales.nhs.uk and Local Health Board web sites.

3.6 Responsibilities

Referrers should:

- Inform the patient when treatment is not routinely funded or outside the criteria in this policy;
- Refer via the agreed pathway

The clinician considering treatment should:

- Discuss all alternative treatments with the patient;
- Advise the patient of any side effect and risks of the potential treatment;
- Inform the patient when treatment is not routinely funded or outside of the criteria in the policy;
- Confirm that NHS Wales has a contractual agreement in place for the treatment.

In all other circumstances an IPFR request will need to be made and approval given before assessment/treatment can proceed.

4. Putting things right raising a concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided. The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel;
- If the patient or their representative is not happy with the decision of the All Wales IPFR Panel the patient and/or their representative has a right to ask for this decision to be reviewed. The grounds for the review, which are detailed in the All Wales Policy: Making Decision on Individual Patient Funding Requests (IPFR), must be clearly stated. The review should be undertaken, by the patient's Local Health Board; or
- When a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

5. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment. The Assessment has shown that there will be equal access for men and women. In respect of transgender, it reflects the necessary links to the Gender Dysphoria Pathway and the findings of the EQiA has been taken into account.

Annex (i)– Checklist

Specialised Services Policy CP69 – Breast Surgery Procedures

The following checklist should be completed for every patient to whom the policy applies:

- i) Where the patient meets the criteria **AND** the procedure is included in the contract **AND** the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.
- ii) The patient meets the criteria **AND** is received at an agreed centre, but the procedure is not included in the contract. The checklist must be completed and submitted to WHSSC for prior approval to treatment.
- iii) The patient meets the criteria but wishes to be referred to a non contracted provider. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration.
- iv) The patient does not meet criteria, but there is evidence of exceptionality. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration for treatment.

To be completed by the referring gatekeeper or treating clinician

The following checklist should be completed for **all patients to whom the policy applies**, before treatment, by the responsible clinician.

Please complete the appropriate boxes:

Patient NHS No:		
Patient is Welsh Resident	Post Code:	
Patient is English Resident registered with NHS Wales GP	GP Code:	
Patient meets following access criteria for treatment:	Yes	No
Patients should be at least 18 years of age AND		
Patient meets the access criteria for:		
Female breast reduction (reduction mammoplasty) (see section 3.2.1 and Annex (ii))		
Male breast reduction for gynaecomastia (see section 3.2.2 and Annex (iii))		
Breast Enlargement (augmentation mammoplasty)(see section 3.2.3 and Annex (iv))		
Breast uplift (Mastopexy) (see section 3.2.4)		
Mastectomy associated with Gender Reassignment Surgery (see section 3.2.7)		
Patient wishes to be referred to non-contracted provider		
<i>If the patient wishes to be referred to a non-contracted provider an Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided on the basis of exceptionality. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&iid=181455</i>		
Patient does not meet access criteria but is exceptional		
<i>An Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided as an exception. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&iid=181455</i>		

Name: _____ **Designation:** _____

Signature: _____ **Date:** _____

	Name (printed):	Signature:	Date:	Yes	No
Authorised by TRM Gatekeeper					
Authorised by WHSSC Patient Care Team					
Patient Care Team/IPFR/TRM Reference number:					



Annex (ii)– Referral form Female Breast Reduction



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Referral form for services not usually available on the NHS in Wales

Cosmetic surgery (surgery undertaken exclusively to improve appearance) will not normally be commissioned in the absence of previous trauma, disease or congenital deformity. Referrers will need to provide clinical detail with regards to the possible effect surgery will have in restoration of function.

(Female)

BREAST REDUCTION / REDUCTION MAMMOPLASTY

Patient Surname		
Patient Forename(s)		
Patient DOB		
Patient NHS No:		
Patient Hospital No:		WHSSC use

It is essential referrers provide detail with regards to the medical management of the following, including frequency, efficacy and dates of treatment.

Symptoms	Yes(✓) / No(x)	Comments	WHSSC Use
Neck or Back ache			
Mastalgia			
Severe intertrigo			
Other (specify)			

Morphology	These measurements will need to be taken within a month of the referral.			
Height (M)		Fulllest part of breast measurement (cm's)		
Weight (Kg)		Under-bust Measurement (cm's)		
Body Mass Index				

Has the patient been professionally fitted with a brassiere?	
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Other factors to be considered	
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Referrer Signature		Date	
Referrers Position			
Referrers Address			

Sent date	Return date	Case officer	Decided date	Decision



Annex (iii)– Referral form Male Breast Reduction



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Referral form for services not usually available on the NHS in Wales

Cosmetic surgery (surgery undertaken exclusively to improve appearance) will not normally be commissioned in the absence of previous trauma, disease or congenital deformity. Referrers will need to provide clinical detail with regards to the possible effect surgery will have in restoration of function.

(Male)

BREAST REDUCTION / REDUCTION MAMMOPLASTY

Patient Surname		
Patient Forename(s)		
Patient DOB		
Patient NHS No:		
Patient Hospital No:		WHSSC use

Morphology		
Height (M)		
Weight (Kg)		
Body Mass Index		

How long has patient had gynaecomastia?	
Details of screening for endocrinological/ drug induced gynaecomastia	
Other factors to be considered	

Referrer Signature		Date	
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Sent date	Return date	Case officer	Decided date	Decision

Annex (iv) – Referral form Breast Augmentation



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Referral form for services not usually available on the NHS in Wales

Cosmetic surgery (surgery undertaken exclusively to improve appearance) will not normally be commissioned in the absence of previous trauma, disease or congenital deformity. Referrers will need to provide clinical detail with regards to the possible effect surgery will have in restoration of function.

BREAST AUGMENTATION/ Asymmetry

Patient Surname		
Patient Forename(s)		
Patient DOB		
Patient NHS No:		
Patient Hospital No:		WHSSC use

Indication	Yes (✓) / No(x)	Comments	HCW Use
Previous mastectomy or excisional breast surgery.			
Trauma to breast during/after development.			
Congenital amastia (total failure of breast development)			

Morphology: Date Measurements taken			
Height:	Weight:	BMI:	
Fullest part of breast measurement			
Under-bust Measurement			

Other factors to be considered	
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Referrer Signature		Date	
Referrers Position			
Referrers Address			

Sent date	Return date	Case officer	Decided date	Decision
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