BREAST RECONSTRUCTION POST CANCER CRITERIA BASED ACCESS (CBA) POLICY

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Application Form	EBI Generic application form if appropriate to apply

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VERSION CONTROL

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DOCUMENT CHANGE HISTORY		
Version	**Date**	**Comments**
1.1	11 June 19	
2	30 Aug 19	Final agreed Policy
3	2 Jan 2020	Template update & CCPF, removal of IFR replaced with EBI
2020.v3a	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.v3b	March 2023	Wording change 11.5
2223.v3c	November 2023	3-year review. Wording change 2.33
2324.v4	June 2024	Logo change with amendment to website link and clinical exceptionality wording on 4.6

Equality Impact Assessment (EIA)	
Quality Impact Assessment QIA	
Sponsoring Director:	Dr Bernie Marden
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1 GENERAL PRINCIPLES (CBA)

1.1 Treatment should only be given in line with these general principles. Where patients are unable to meet these principles, in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB's Evidence Based Interventions Service (EBI) by submission of an EBI application form

1.2 Clinicians should assess their patients against the criteria within this policy prior to a referral and/or treatment

1.3 Treatment should only be undertaken where the criteria have been met and there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment

1.4 Referring patients to secondary / community care without them meeting the criteria or funding approval not secured not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment

1.5 On limited occasions, the ICB may approve funding for an assessment only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meet the criteria to access treatment in this policy

1.6 Patients should be advised being referred does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment

1.7 The policy does not apply to patients with suspected malignancy who should continue to be referred under 2 week wait pathway rules for assessment and testing as appropriate

1.8 Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be encouraged to lose weight further prior to seeking surgery. https://www.sciencedirect.com/science/article/pii/S1198743X15007193 (Thelwall, 2015)

1.9 Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing

2 POLICY CRITERIA – CRITERIA BASED ACCESS (CBA)

RETROSPECTIVE, PROSPECTIVE AND PART FUNDING
The Commissioner does not fund retrospectively or prospectively (where a patient may in future benefit from a treatment that is not currently needed). The Commissioner does not part-fund treatment or fund equipment ordered prior to the panel's approval.

Patients who are not eligible for treatment under this policy, please refer to section 4 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS on how to apply for funding with evidence of clinical exceptionality

2.1 BREAST RECONSTRUCTION POST CANCER- BREAST AFFECTED BY CANCER ONLY

Funding for surgery will only be provided by the ICB for patients meeting all criteria as set out below:

a) Patients must be assessed by a multidisciplinary team (MDT) **AND**

b) The MDT must confirm that:
It recommends a specific treatment for a patient having considered all the available alternatives **AND**

c) The potential benefits outweigh potential harm

2.2 In addition to the MDT criteria above (criteria b-c) the following criteria must be met:

d) The patient has completed treatment for breast cancer, resulting in the removal of breast tissue, within the last 5 years dating from the MDT recommendation **AND**

e) This surgery is to reinstate the affected breast to an appearance reasonably equivalent to pre-breast cancer condition, acknowledging that an identical shape/ contour cannot be achieved.

NB. Patients with inflammatory breast cancer are required to wait an additional 2-year post treatment before being eligible to commence surgery therefore this funding will be extended until 7 years for those patients. Extensions to this time limit will require the lead surgeon to contact the commissioner seeking approval for patients to access the pathway, although approval will not be unreasonably withheld.

2.3 BREAST RECONSTRUCTION POST CANCER

2.3.1 CONTRALATERAL BREAST REBALANCING SURGERY (Surgery to breast unaffected by cancer to achieve symmetry)

Funding for surgery will only be provided by the ICB for patients meeting all criteria as set out below:

a) Patients must be assessed by a multidisciplinary team (MDT). The expectation of the ICB is that the MDT makes the most clinically appropriate decision and cannot recommend surgery purely for cosmetic reasons.

b) The MDT confirms that:
It recommends surgery to the unaffected breast for this patient having considered all the available alternatives **AND**

c) The potential benefits outweigh potential harm

2.3.2 In addition to the MDT criteria above (criteria b-c) the following criteria must be met:

The surgery to the contralateral breast is required for cosmetic breast rebalancing purposes as appropriate.

NB. Surgery to the contralateral breast is to be undertaken within the pre-agreed 3 surgical episodes for both breasts. All 3 surgical procedures must be completed within 2 years of the first procedure. If additional surgery is required, please contact the EBI team for further guidance.

2.3.3 **Breast Implant Removal and Replacement**

Both breast implants can be removed **OR** removed and replaced during the same surgery for the following clinical indications with the patients consent:

a) One OR both implants have ruptured.

b) One OR both implants have grade 3 or 4 capsular contracture.

c) One OR both implants are complicated by recurrent implant infection OR Seroma.

d) The patient develops Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

2.4 **Complications following surgery**

Patients are entitled to access surgery following complications for a timescale of no greater than 24 months following the date of the last surgery. This timescale is considered appropriate to allow for post-operative healing. In the event of delays beyond this timescale, managing clinicians will need to contact the commissioners for advice and consideration of extensions

3 Background

There are a number of different surgical procedures that may take place in order to remove the cancerous tissue in the breast and then to repair the breast following such surgery. For people diagnosed with breast cancer, removal of any cancerous tissue in the breast forms part of a treatment pathway. The tissue that is removed can be limited to a localised amount of breast tissue around the cancer (lumpectomy) or can be the full removal of a breast (mastectomy). These procedures are used to treat breast cancer in both females and males.

Following treatment for breast cancer, a person may wish to have the cosmetic appearance of the breast improved. Breast appearance can be improved by wearing a prosthesis and specialist bras. There are also numerous surgical options available for breast reconstruction after the removal of cancerous breast tissue. Support is given to patients who are preparing for surgery, and this can help prepare for both the physical and emotional impact of such surgery.

3.1 PURPOSE OF BREAST RECONSTRUCTION SURGERY POST CANCER

The purpose of breast reconstruction surgery is to allow the surgeon to rebuild the affected breast to give an appearance of a natural contour. This is to bring the breast to a level reasonably equivalent to its appearance prior to the removal of the cancerous tissue. Surgery to improve on the appearance of the breasts to a superior level pre breast cancer treatment is not commissioned.

3.2 CONTRALATERAL BREAST SURGERY

Surgery to the breast unaffected by cancer is allowed when the reconstructive surgery requires the surgeon to rebalance a disproportionate size variation between the affected and the contralateral unaffected breast to produce a more symmetrical appearance.

The decision to treat the contralateral breast must be taken by a multidisciplinary team to agree the clinical appropriateness of any treatment in line with the published criteria.

This policy is only appropriate for patients on the post cancer breast reconstruction pathway. For all other non-post cancer related breast surgery requirements, please refer to the correct policy:

- Breast surgery- female
- Breast surgery – male
- Cosmetic surgery
- Liposuction to reduce fat pockets and deposits
- Skin contouring

3.3 POLICY DEVELOPMENT

This policy has been developed with the guidance and support of local breast reconstruction surgeons within Somerset and the wider SWAG Cancer Alliance. In developing this policy local breast surgeons have advised that a patient may need up to 3 operations in order to achieve a good outcome. This policy supports “getting it right first time” as good practice. This includes surgery to both the affected breast and the unaffected breast, when it is clinically agreed by the MDT that breast rebalancing surgery is required.

If additional surgery is required over and above these 3 recommended surgeries, guidance should be sought from the Evidence Based Interventions Panel on a case-by-case basis before proceeding. Where the Evidence Based Interventions, Panel identify a trend and/or a cohort of patients who require more than the 3 agreed surgical treatments, a policy review will be carried out in line with the NHS Somerset ICB policy review process.

3.4 OTHER CONSIDERATIONS

Inflammatory breast cancer

Patients with Inflammatory breast cancer are required to wait 2 years post treatment before being eligible to commence surgery. For these patients, point 3 of the criteria below will commence after 2 years have passed, extending the overall timeframe from 5 to 7 years. This has been agreed as appropriate following consultation with local surgeons. If treatment is required outside of this timeframe, the clinical referrer is required to please contact the Evidence Based Interventions team for guidance on to how to proceed.

3.5 BENIGN LUMP REMOVAL FROM BREASTS

The removal of benign breast lumps is considered under the benign skin lesion policy and, therefore, reconstruction of breast tissue following the removal of benign breast lumps falls outside of the scope of this policy. Such requests may be considered by the Evidence Based Interventions Panel under the appropriate breast surgery/ cosmetic surgery policy.

3.6 BREAST SURGERY IN MALES

Breast cancer is rare in men. There are about 390 men diagnosed each year in the UK. This compares to around 54,800 cases in women. There are some similarities between male breast cancer and female breast cancer. But there are also important differences between the two. The most common type in both women and men is called “invasive breast carcinoma - no special type”. Some men develop rarer types of breast cancer, such as inflammatory breast cancer. Or they might develop conditions related to breast cancer, but these are very uncommon.

3.7 NIPPLE TATTOO

Some patients prefer to have a nipple tattoo instead of having a new nipple- this is routinely commissioned and not subject to this restricted policy.

3.8 RISKS OF BREAST SURGERY

All forms of surgery carry some degree of risk. Complications that can affect anyone who has surgery include:

An adverse reaction to the anaesthetic

- Excessive bleeding
- Risk of infection
- Developing blood clots

3.9 COMPLICATIONS REQUIRING ADDITIONAL SURGERY

As with all surgery, complications may occur which result in additional surgery being required. such complications include, but are not limited to, post-operative infections and rupture to breast implants requiring their removal and reinsertion. Additional surgery is permitted without the need for additional funding to be secured where this request is documented by the multidisciplinary team as being clinically appropriate and within the scope of this policy. The commissioner requires this information to be clearly recorded within a patient's record to support the criteria-based access audit process and possible further policy development.

Patients are entitled to access surgery following complications for a timescale of no later than 24 months following the date of the last surgery. This timescale is considered appropriate to allow for post-operative healing.

Any requests for assessment and/or treatment after 24 months will be considered inline with the most appropriate commissioning policy at such time, and funding will be required to be sought by the clinical referrer in advance of any referral for treatment, although approval will not be unreasonably withheld.

3.10 EXCLUSIONS

Cosmetic enhancements following reconstructive surgery do not fall within the scope of this policy. Funding requests for cosmetic surgery may be submitted to the Evidence Based Interventions (EBI) team, using the appropriate EBI application form.

Other examples of surgery considered as being outside the scope of this policy are (But not limited to):

- Breast uplift/ mastopexy to the unaffected breast following normal effects of aging
- Nipple repositioning on the unaffected breast

4 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

4.1 Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or Consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy

4.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required

4.3 Applications cannot be considered from patients personally

4.4 Only electronically completed EBI applications will be accepted to the EBI Service

4.5 It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the EBI service. This will reassure the service that the patient has a reasonable expectation of the outcome of the application and its context

4.6 EBI funding application are considered against clinical exceptionality. To eliminate discrimination for patients, **social, environmental, workplace, and non-clinical personal factors cannot be taken into consideration.**

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB EBI webpage Evidence Based Interventions - NHS Somerset ICB and click on the section titled Generic EBI Pathway.

4.7 Where appropriate photographic supporting evidence can be forwarded with the application form

4.8 An application put forward for consideration must demonstrated some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:

- Significantly different to the general population of patients with the condition in question
- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

5 ACCESS TO POLICY

5.1 If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067

5.2 **Or write to us**: NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

6 REFERENCES

The following sources have been considered when drafting this policy:

6.1 http://www.nhs.uk/Conditions/Mastectomy. (n.d.). Retrieved from NHS Choices: http://www.nhs.uk/Conditions/Mastectomy/Pages/Introduction.aspx

6.2 COMPLICATIONS OF POSTMASTECTOMY BREAST RECONSTRUCTIONS IN SMOKERS, EX-SMOKERS, AND NONSMOKERS

HTTPS://WWW.NCBI.NLM.NIH.GOV/PUBMED/11214048

Padubidri AN[1], Yetman R, Browne E, Lucas A, Papay F, Larive B, Zins J.

"Complications were significantly more frequent in smokers. Mastectomy flap necrosis was significantly more frequent in smokers, regardless of the type of reconstruction. Breast reconstruction should be done with caution in smokers. Ex-smokers had complication rates similar to those of nonsmokers. Smokers undergoing reconstruction should be strongly urged to stop smoking at least 3 weeks before their surgery."

6.3 NHS Health Mastectomy http://www.nhs.uk/Conditions/Mastectomy/Pages/Introduction.aspx

6.4 stages-types-grades/types/male-breast-cancer. Retrieved from https://www.cancerresearchuk.org/about-cancer/breast-cancer/types/male-breast-cancer

Impact of obesity on the risk of wound infection following surgery: results from a nationwide prospective multicentre cohort study in England. Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases, , vol. 21, no. 11

6.5 NICE Guidance Recommendations | Early and locally advanced breast cancer: diagnosis and management | Guidance | NICE

6.6 ABS, BAPRAS and Breast Cancer Now guidance

Appendix 1

BREAST RECONSTRUCTION POST BREAST CANCER & RISK REDUCTION SURGERY POLICY

(Including additional procedures)

EXCEPTIONAL FUNDING/PRIOR APPROVAL REQUIRED WHERE INDICATED-

EBI FUNDING APPLICATIONS TO BE COMPLETED BY SECONDARY CARE

Breast reconstruction surgery post breast cancer

Patients who have been treated for cancer will be provided with reconstruction surgery in line with national guidelines.

The primary surgical breast reconstruction following cancer treatment does not require any funding approval for 5 years after diagnosis. This includes the affected breast and a single surgical procedure to achieve symmetry in the contralateral breast.

- **Further surgery to the affected breast after 5 years requires an Evidence Based Intervention (EBI) funding application -** except in cases of grade 3/4 capsule contracture where prior approval is not required
- **Symmetrising surgery for the contralateral breast after 5 years** following initial planned treatment – **requires EBI approval**.
- **Fat transfer procedures (lipofilling)** – funding approval not required for up to 2 cycles of fat transfer for the affected breast within the first 5-year period. Further lipofilling or lipofilling after 5 years **requires EBI approval**.

Risk Reduction Surgery

- Risk reduction surgery is an option for patients with a confirmed high risk of developing breast cancer following genetic counselling/testing-**Prior Approval not required.**
- For patient at confirmed moderate risk, applications will be considered through the EBI process.
- For patients with low risk, risk reduction surgery is not normally funded.