Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Meeting of BNSSG ICB Board Meeting

Date: Thursday 2nd March 2023
Time: 12:30pm
Location: The Park Community Centre, Daventry Road, Knowle, Bristol, BS4 1DQ

Agenda Number:	6.1
Title:	Clinical Commissioning Policies - Breast
Purpose: Decision	
Key Points for Discussion:	
The paper provides an overview of proposed changes to the organisation's commissioning stance for six breast-related policies. Three policies are changing, alterations include: • Policy name change, from Prophylactic Mastectomy to Risk Reducing Mastectomy, • A wider scope under the Female Breast policy for long-term treatment to be funded under certain circumstances, and • A wider scope under the Breast Reconstruction post-Cancer policy for long-term treatment to be funded under certain circumstances. The ICB Board is asked to consider and approve for adoption, the revised commissioning policies.	
Recommendations:	1. Continue to use the current commissioning policies for Breast Surgery Male and MRI Breast Screening. 2. Approve changes to the current commissioning policies for Risk Reducing Mastectomy, Breast Surgery Female and Breast Reconstruction post-Cancer. 3. Remove the One Step Nucleic Acid Amplification (OSNA) policy.
Previously Considered By and feedback:	Proposed policies have been reviewed by BNSSG ICB Commissioning Policy Review Group who have recommended continuation, adoption and removal of policies as outlined above.
Management of Declared Interest:	There have been no conflicts declared by any individual involved in the review, nor any of the committees who have reviewed the proposed policies.
Risk and Assurance:	There is a risk that if the proposed policy changes are not adopted, the ICB will remain open to legal challenges under the Equality Act. The current Female Breast policy and Breast Reconstruction post-Cancer commissioning policy provide no clear clinical rationale why long-term treatment would not be funded under certain circumstances and can be seen as over-restrictive. There is a risk that broadening the scope of the criteria in the two policies could lead to an initial increase in activity. This has been mitigated by funding to clear the backlog of individuals who would

	need this form of surgery. Work has been done to identify as far as possible the likely impact of changes. Activity will be monitored and should activity increase beyond current projections, a rapid policy review could be considered.
Financial / Resource Implications:	No net savings are anticipated through the implementation of these policies. Due to the proposed changes, it is likely that expenditure connected to Female Breast policy and Breast Reconstruction post-Cancer commissioning policy will increase in the first year. Once the backlog of patients requiring surgery has been cleared, it is possible that annual costs will be stable.
Legal, Policy and Regulatory Requirements:	There are no known legal implications for any of the policies presented.
How does this reduce Health Inequalities:	The revised policies presented address the current known issues around equitable access to the long-term management and support of individuals who have had NHS commissioned reconstructive breast surgery.
How does this impact on Equality & diversity	An Equality Impact Assessment (EIA) has been completed and signed off by the ICB's Equalities Lead for each of the policies under consideration. Adjustments to the current Female Breast policy and Breast Reconstruction post-Cancer commissioning policy address the current inequality for individuals who are on a non-Cancer pathway.
Patient and Public Involvement:	A Patient and Public Involvement (PPI) Assessment has been completed and signed off by the ICB's PPI Lead for each of the policies under consideration.
Communications and Engagement:	Communication to primary and secondary care clinicians will be undertaken to explain the changes to the commissioning stance.
Author(s):	Chris Moloney (Commissioning Policy Development Manager) Peter Goyder (Clinical Lead for Policy Development and Exceptional Funding) Jude Hancock (Senior Clinical Effectiveness Programme Manager)
Sponsoring Director / Clinical Lead / Lay Member:	Jo Medhurst (Chief Medical Officer)

Agenda item: 6.1

Report title: ICB Breast surgery policies (Clinical Commissioning Policies)

1. Background

The Bristol, North Somerset and South Gloucestershire Integrated Care Board's (BNSSG ICB) Commissioning Policy Review Group (CPRG) requires that each commissioning policy is reviewed three years from the date of adoption. BNSSG ICB's six current breast commissioning policies have been reviewed in line with this requirement. The Commissioning Policy Development (CPD) team are responsible for initiating and leading the review of commissioning policies.

The review of the organisation's six breast policies was due to be completed in 2021. However, due to a range of issues including the impact of COVID-19 on provider's ability to engage, low staffing levels within the CPD team, and transition from a Clinical Commissioning Group (CCG) to an Integrated Care Board (ICB) the reviews were not completed until December 2022.

In the development of these proposed policies, the CPD team have engaged with breast specialists from North Bristol Trust (NBT) and University Hospitals Bristol and Weston (UHBW).

The six breast policies under review were discussed at length by CPRG in January 2023. Table 1 below summarises the policies that have been reviewed and discussed with the recommendation for each policy being made to the ICB board.

Table 1. Policy and recommendations

Policy	Recommendation to ICB board
Risk Reducing Mastectomy	Approve changes and adopt
Breast Reconstruction post-Cancer	Approve changes and adopt
Breast Surgery Female	Approve changes and adopt
Breast Surgery Male	No change to current policy, adopt
MRI Breast Screening	No change to current policy, adopt
One Step Nucleic Acid Amplification (OSNA)	Remove policy

2. Overview of Policies requiring approval of changes and adoption

Risk Reducing Mastectomy

Clinicians at UHBW and NBT clinicians agreed that no changes to the policy criteria were required, and it would be appropriate to continue to follow the NICE guidelines. The clinical team however requested the name of the policy change from Prophylactic Mastectomy to Risk Reducing Mastectomy. The CPRG agreed with this policy name change.

Breast Reconstruction post-Cancer

The current policies for Breast Surgery were adopted in 2018. When the policies were developed, it was considered that the best use of resource would be to fund breast reconstruction, but not long-term treatment. Priority was given to patients on a cancer pathway to allow reconstruction. There is no clear clinical rationale why long-term treatment would not be funded under certain circumstances. Clinicians at NBT have engaged with the CPD team to develop a more equitable policy. The CPRG agree with the following proposed change.

Proposed Change

- Patients who have had implants not under the NHS who have developed leakage and granulomas have formed, usually in the axilla can have implant removal but not replacement under the NHS.

Changes to this policy and the Female Breast Surgery policy (see next section), will have impact activity for cohorts managed under the current policies. Activity for breast reconstruction post-Cancer since financial year 20/21 held by the BNSSG Business Intelligence (BI) team is shown in Figure 1. Financial impacts are discussed in section 5 (page 6).

Figure 1. Activity for Breast Reconstruction post-Cancer

Activity	2020/21	2021/22	2022/23
Actual	1	4	1
FOT			12

*FOT = Forecast Out Turn

Breast Surgery Female

As previously stated, the current policies for Breast Surgery were adopted in 2018 and there is no clear clinical rationale why long-term treatment would not be funded under certain circumstances. Clinicians at NBT have engaged with the CPD team to develop a more equitable policy. The CPRG agree with the following proposed change.

Proposed Changes

- Patients who have had breast reconstruction surgery would be able to access long term support and surgical intervention for the reasonable ongoing support of the reconstruction surgery including implant removal and replacement or transition to the most appropriate reconstruction where required.

- Patients who have had a reconstruction following breast cancer privately but who are no longer covered in the private sector would be supported in an ongoing manner as if their surgery was initially performed in the NHS.

- All surgery for these patients should be agreed using the Oncoplastic MDT to ensure that the surgery is appropriate, proportionate and fits within the policy in place at the time.

Activity for breast surgery female since financial year 20/21 held by the BNSSG BI team is shown in Figure 1. It is difficult to accurately project the impact proposed changes to the policy will have on local activity and expenditure (discussed in section 5, page 6). Much of the treatment proposed in the policy is not currently undertaken locally and, therefore, there is no reliable data to use for the basis of projections.

Figure 2. Activity for Breast Surgery Female

Activity	2020/21	2021/22	2022/23
Actual	31	43	7
FOT			84

*FOT = Forecast Out Turn

To understand the impact, the CPD team have asked clinicians to provide some clarity on the likely impact. The CPD team have also obtained the number of Exceptional Funding Request (EFR) applications for these procedures. It is recommended the figures obtained are treated as the minimum number of additional patients that might require treatment.

It is estimated that there are approximately 3 patients who have had reconstructive surgery provided by the NHS for varied reasons. This figure is based on the current number of patients significant issues who are seen by the surgical team.

It is estimated that there will approximately be 30 patients who would need this form of surgery per annum once the backlog has been addressed. This is based on national data regarding the number of women requiring revisions to breast reconstruction within 5-8 years of the initial surgery.

3. Overview of Policies with no changes required

Breast Surgery Male

Through engagement with relevant local clinicians and the CPRG it has been agreed that this intervention should remain unfunded. This is in line with the recommendations of NHS England's 2019 evidence-based intervention program.

MRI Breast Screening

Through engagement with relevant local clinicians and the CPRG it has been agreed that no changes were required, and it would be appropriate to continue to follow the NICE guidelines.

4. Overview of Policy for removal

One Step Nuclei Acid Amplification (ONSA)

This policy was developed at a time when OSNA was thought to be a major breakthrough and could be very widely used. Evaluation of OSNA showed that there is only a small cohort where there are really clear benefits. This technology is not used in routine practice in BNSSG and there is no desire to return to its regular use. Any use would be exceptional. For these reasons the policy does not have any benefit and should be retired. This decision has been made working in conjunction with the breast and oncoplastic surgeons locally.

5. Financial resource implications

The financial resource implications relate to the two policies where criteria changes are proposed, Female Breast and Breast Reconstruction post-Cancer, where long-term treatment would in future be funded under certain circumstances.

Breast Reconstruction post-Cancer

Financial cost for breast reconstruction post-cancer since financial year 20/21 held by the BNSSG BI team is shown in Figure 3. Changes to this policy and the Female Breast Surgery policy, will have an impact on activity for cohorts managed under the current policies. Therefore, financial projections for the likely impact of this policy change, are factored into projections for the Female Breast Surgery policy.

Figure 3. Financial cost for Breast Reconstruction post-Cancer

Finance	2020/21	2021/22	2022/23
Actual	£84	£32,480	£8,120
FOT			£97,440

*FOT = Forecast Out Turn

Breast Surgery Female

Financial cost for breast surgery female since financial year 20/21 held by the BNSSG BI team is shown in Figure 4. It is difficult to accurately project the impact proposed changes to the policy will have on local activity and expenditure. Much of the treatment proposed in the policy is not currently undertaken locally and, therefore, there is no reliable data to use for the basis of projections.

Figure 4. Financial cost for Breast Surgery Female

Finance	2020/21	2021/22	2022/23
Actual	£78,767	£177,631	£26,769
FOT			£321,228

*FOT = Forecast Out Turn

To understand the impact, the CPD team have asked clinicians to provide some clarity on the likely impact. The CPD team have also obtained the number of EFR applications for these procedures. It is recommended the figures obtained are treated as the minimum number of additional patients that might require treatment.

It is estimated that there are approximately 3 patients who have had reconstructive surgery provided by the NHS for varied reasons. This figure is based on the current number of patients significant issues who are seen by the surgical team.

It is estimated that there will approximately be 30 patients who would need this form of surgery per annum once the backlog has been addressed. This is based on national data regarding the number of women requiring revisions to breast reconstruction within 5-8 years of the initial surgery.

Adopting the proposed changes to the commissioning policy could lead to an initial minimal increase of £131,432. This figure is based on the average tariff for breast surgery.

As noted above, much of the treatment proposed in the policy is not funded within BNSSG. It is, however, possible that some patients are receiving treatment that is not covered by the ICB's current commissioning policy. Therefore, the cost of current potential 'unfunded' activity should be included in any projection. Changes to the policy could lead to annual expenditure of up to £211,663 for Breast Surgery. However, it should be noted that this is a maximum projection, given the limitations of the BI data.

Once the backlog of patients requiring surgery has been cleared, it is possible that annual costs will decrease. However, this data is reliant on projections from rough estimates delivered by the clinical teams. As the procedures proposed are not currently funded, there is no reliable data to draw projections from. Therefore, it should be assumed that activity could be higher than estimated by a factor of 2.

Note: This is a joint projection that also covers the Breast Reconstruction Post Cancer policy proposed changes.

Mitigations

The CPD team have been advised by the ICB's Chief Finance Officer (CFO) that funding for the likely increase in patients from changing these two policies in the 2023/24 financial year can be managed through the Elective Services Recovery Funding in the 23/24 financial year. The surgical team at NBT are confident they can work though how to manage the possible extra activity.

6. Legal implications

There are no known legal implications for any of the policies presented.

7. Risk implications

As there were no clear clinical rationale why long-term treatment would not be funded under certain circumstances for the current Female Breast and Breast Reconstruction post-Cancer policies the ICB may be at risk for not providing equitable treatment to individual who would benefit under certain circumstances. The new policies are more equitable enabling long-term treatment to be funded under certain circumstances for applicable individuals.

A small number of complaints and enquiries from MPs and the public have been received since the current policy was adopted. Therefore, it is likely that these complaints will continue should the current commissioning stance remain in place.

There is a risk that broadening the scope of the policies, could lead to an increase in activity. Work has been done with the clinicians and BI team as far as possible to estimate the likely activity impact of changes. Similarly, the CPD team have spoken with the ICB's CFO to identify funding to cover this potential increase in activity.

8. How does this reduce health inequalities

The proposed changes to the Female Breast and Breast Reconstruction post-Cancer policies will have a positive impact on protected characteristics, making the policy more equitable.

9. How does this impact on Equality and Diversity?

The ICB's Equalities Lead has reviewed and signed off the three policies with changes, and the two policies to continue (see Table 1, page 3).

The changes to the Female Breast and Breast Reconstruction post-Cancer policies resolves the discriminatory issue against not funding long-term treatment under any circumstances. The proposed policies do not negatively impact any patient group that shares a protected characteristic. These policies use clinical evidence and provides a clear rationale for people who will be considered for treatment and assessment.

10. Consultation and Communication including Public Involvement

The ICB's PPI lead has reviewed and signed off the three policies with changes, and the two policies to continue (see Table 1, page 3). The PPI lead stated, "there is no change to the range or manner in which the services are delivered, therefore there is no need to carry out a full PPI review".

The relevant clinicians at NBT and UHBW have been actively involved in the review of the commissioning policies. Communication to primary and secondary care clinicians will be undertaken to explain the changes to the commissioning stance.

Appendices

Appendix 1 – Proposed Commissioning Policies (Attached)

Appendix 2 – Equality Impact Assessments (Attached)

Breast Surgery (for females)

Exceptional Funding Request

Before consideration of referral for management in secondary care, please review advice on the Remedy website (https://remedy.bnssg.icb.nhs.uk/adults/breast/) or consider use of advice and guidance services where available.

Breast Surgery (female) is not routinely commissioned.

Breast implant surgery (post cancer treatment)

Patients who have been treated for cancer with a complete mastectomy will be provided with reconstruction surgery in line with national guidelines. There are many techniques available to improve a patient's appearance after a mastectomy. The final choice depends on patient desires, body habitus, available tissue, appearance of the opposite breast, and the health of the patient. The realistic goal of reconstructive surgery should always be to as far as possible replicate the appearance of the original breast and not the perfect replacement of the breast.

The primary surgical breast reconstruction for a patient who has undergone a mastectomy due to cancer does not require funding approval. However, the ICB will only fund planned breast surgery that has been agreed at an oncoplastic multi-disciplinary team meeting.

Patients With Axillary Granulomas

Patients who have had privately placed breast implants for cosmetic reasons that have ruptured and developed granulomas (usually axillary), are entitled to implant removal only.

Removal of axillary granulomas is not routinely commissioned.

Complications Following Surgery for NHS commissioned breast reconstruction surgery non-cancer

Patients are entitled to access surgery following significant complications associated with their breast reconstruction.

- Patients in whom further surgery for complications is considered **MUST** be discussed by the Oncoplastic MDT. The MDT must agree that the proposed surgery is appropriate and that the benefits outweigh the risks.

For more guidance, please see https://remedy.bnssg.icb.nhs.uk/adults/breast/

Outside the scope of this policy

Breast Surgery for all patients post Breast Cancer is not covered by this policy.

Breast surgery for males including treatment of gynaecomastia is covered by a separate clinical policy.

Breast surgery for patients on the gender dysphoria pathway is the commissioning responsibility of NHS England and is not subject to this policy.

BNSSG ICB is responsible for making the best use of the NHS funds allocated to us to meet the health needs of our local population. The demand for services is greater than the resources available and therefore we must prioritise the use of funds carefully. Our approach is to prioritise commissioning treatments, operations or drugs that are most effective in meeting the health needs of the population. All operations carry significant risks and where symptoms are mild or moderate it is likely that the risks outweigh the benefits. Not all conditions progress and when symptoms can be managed conservatively, that is the safest option.

The ICB does not commission Breast Surgery (for females).

BNSSG ICB has determined that when considering its priorities, the risks, effectiveness, and cost of this procedure does not provide overall value.

Breast Surgery (for females) – Plain Language Summary

Breast surgery includes all surgeries to alter or improve the appearance of female breasts, including:

- Breast implant surgery including augmentation/provision, revision or extraction of breast implants
- Breast asymmetry correction surgery
- Breast reduction
- Breast mastopexy or uplift
- Correction of inverted nipples

This policy has been developed with the aid of the following references:

1. NHS England (2019) Evidence Based Interventions, Breast Reduction Surgery www.england.nhs.uk
2. National Health Service (2019) Health A to Z: Breast reduction on the NHS [online] www.nhs.uk/conditions
3. National Library of Medicine (2011) The impact of obesity on breast surgery complications (21666541) www.pubmed.ncbi.nlm.nih.gov

4. National Library of Medicine (2009) The impact of breast reduction surgery on low-back compressive forces and function in individuals with macromastia (20009823) www.pubmed.ncbi.nlm.nih.gov
5. National Library of Medicine (2003) An investigation of the suitability of bra fit in women referred for reduction mammoplasty (12859918) www.pubmed.ncbi.nlm.nih.gov
6. National Library of Medicine (2008) Breast size, bra fit and thoracic pain in young women: a correlational study (PMC2275741) www.pubmed.ncbi.nlm.nih.gov
7. National Library of Medicine (2012) Relationship Between Brassiere Cup Size and Shoulder-Neck Pain in Women (PMC3322448) www.pubmed.ncbi.nlm.nih.gov
8. National Library of Medicine (2014) Breast-Related Symptoms Questionnaire (PMC24508223) www.pubmed.ncbi.nlm.nih.gov
9. National Library of Medicine (2011) Obesity in mammaplasty: a study of complications following breast reduction (PMC 20682461) www.pubmed.ncbi.nlm.nih.gov
10. National Library of Medicine (2012) Additional benefits of reduction mammaplasty: a systematic review of the literature (PMC 22090252) www.pubmed.ncbi.nlm.nih.gov
11. National Library of Medicine (2015) How Does Volume of Resection Relate to Symptom Relief for Reduction Mammaplasty Patients? (PMC24508223) www.pubmed.ncbi.nlm.nih.gov
12. Royal College of Surgeons (2014) Breast Reduction - Commissioning Guide (PMC24508223) www.rcseng.ac.uk

Connected Policies

Breast Surgery Policy (for male): Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.
Cosmetic Surgery: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.
Skin Contouring: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.
Skin Camouflage: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.
Tattoo Removal: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.

Due regard

In carrying out their functions, the Bristol North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED), and NHSE Evidence-Based Interventions (EBI). This applies to all the activities for which the ICBs are responsible, including policy development and review.

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Integrated Care Board

Document Control

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OPCS Procedure codes

Must have any of (primary only):
B301,B302,B303,B304,B308,B309,B311,B312,B313,B314,B318,B319,B381,B382,B388,B389,B391,B392,B393,B394,B395,B398,B399,B351,B356,B358,B359

Relevant diagnoses for this policy:
ICD10 Code: None

Diagnoses for which the above procedures are permitted:
ICD10 Code: C50, C500, C509, C501, C502, C503, C504, C505, C506, C507, C508, C509D, Z853

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Breast Surgery (for males)

Exceptional Funding Request

Before consideration of referral for management in secondary care, please review advice on the Remedy website (https://remedy.bnssg.icb.nhs.uk/adults/breast/) or consider use of advice and guidance services where available.

Breast Surgery for males is not routinely commissioned.

For more guidance, please see https://remedy.bnssg.icb.nhs.uk/adults/breast/

Outside the scope of this policy

Breast Surgery for all patients post Breast Cancer is not covered by this policy.

BNSSG ICB is responsible for making the best use of the NHS funds allocated to us to meet the health needs of our local population. The demand for services is greater than the resources available and therefore we must prioritise the use of funds carefully. Our approach is to prioritise commissioning treatments, operations or drugs that are most effective

in meeting the health needs of the population. All operations carry significant risks and where symptoms are mild or moderate it is likely that the risks outweigh the benefits. Not all conditions progress and when symptoms can be managed conservatively, that is the safest option.

Breast Surgery (for males) – Plain Language Summary

Breast surgery for male patients can include the following procedures or conditions:

Breast Reduction for Gynaecomastia

Gynaecomastia is common and usually temporary in neonates and adolescent boys. It is thought to occur in about 32 to 36% of men (Lee, 2012).

Gynaecomastia is an enlargement of breast tissue in men. For some people it can be normal. It can also be a side effect of medication or a sign of disease. It is a common feature of obesity. Treatments for painful or embarrassing gynaecomastia can include some medications and surgical procedures.

Gynaecomastia does not usually require treatment. Treating an underlying disorder, or stopping a medication that is likely the cause, may be sufficient, especially if gynaecomastia is relatively recent.

Gender Dysphoria

Breast surgery for patients on the gender dysphoria pathway is the commissioning responsibility of NHS England and is not subject to this policy.

This policy has been developed with the aid of the following references:

1. NHS England (2019) Evidence Based Interventions, Breast Reduction Surgery www.england.nhs.uk
2. National Health Service (2019) Health A to Z: Breast reduction on the NHS [online] www.nhs.uk/conditions
3. National Library of Medicine (2011) The impact of obesity on breast surgery complications (21666541) www.pubmed.ncbi.nlm.nih.gov
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12. Royal College Of Surgeons (2014) Breast Reducation - Commissioning Guide (PMC24508223) www.rcseng.ac.uk

Connected Policies

Breast Surgery Policy (for female): Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.

Cosmetic Surgery: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.

Skin Contouring: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.

Skin Camouflage: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.

Tattoo Removal: Treatment will not be offered under this policy. Clinicians should refer to the intervention specific policy.

Due regard

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Patient and Public Involvement	18th August 2022

OPCS Procedure codes

Must have any of (primary only):
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Breast Reconstruction post-Cancer

(Including Surgery to provide symmetry)

CRITERIA BASED ACCESS

Before consideration of referral for management in secondary care, please review advice on the Remedy website (https://remedy.bnssg.icb.nhs.uk/adults/breast/) or consider use of advice and guidance services where available.

Note: Funding is only supported for the breast affected by cancer.

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

1. Patients must be assessed by a Oncoplastic (MDT).

   AND

2. The Oncoplastic (MDT) must confirm that:

   a) it recommends appropriate options for the patient and has considered all the available alternatives.

   AND

   b) the potential benefits outweigh potential harm.

In addition to the MDT criteria above (Criteria 1 & 2) the following criteria must be met:

3. The patient has required the removal of some or all of their breast tissue as part of their breast cancer treatment.

   AND

4. This surgery is to reconstruct the affected breast to achieve an acceptable cosmetic outcome, acknowledging that reconstructing the breast to achieve the same shape/contour is unlikely to be possible.

NOTE:
Patients will generally be limited to 3 surgeries, and these should ideally be completed within 2 years of the patient starting their reconstructive process (i.e., their 1st reconstruction operation). Any patient in whom more than 3 operations are required MUST be discussed and agreed at the Oncoplastic MDT.

Complications Following Surgery

Patients are entitled to access surgery following significant complications associated with their breast reconstruction.

- Patients in whom further surgery for complications is considered **MUST** be discussed by the Oncoplastic MDT. The MDT must agree that the proposed surgery is appropriate and that the benefits outweigh the risks.

  Patients whose oncoplastic surgery was initially in the private sector who are no longer covered in the private sector will be allowed to access to the pathway for management of significant complications, and for completion of their reconstructive journey if this was not finished in the private sector.

For more information, please see https://remedy.bnssg.icb.nhs.uk/adults/breast/

BREAST RECONSTRUCTION POST-CANCER 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:

1. Patients must be assessed by a Oncoplastic (MDT). The expectation of the ICB is that the MDT recommends clinically appropriate options and does not recommend surgery purely for cosmetic reasons.

   AND

2. The Oncoplastic Team (MDT) confirms that:

   a) it recommends surgery to the unaffected breast for this patient having considered all available alternatives

   AND

   b) the potential benefits outweigh potential harm

In addition to the MDT Criteria above (criteria 1 & 2) the following criterion must be met:

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

NOTE:

1. **Surgery to the contralateral breast should ideally be undertaken within the pre-agreed 3 surgical episodes for both breasts unless there are specific reasons why this is not possible. All cases must be discussed at the Oncoplastic MDT.**

2. **Bilateral mastectomy if supported by the Oncoplastic MDT will be considered as the definitive surgical intervention, rather than reconstruction.**

Complications Following Surgery

Patients are entitled to access surgery following significant complications.

- Surgery for significant complications related to reconstruction will be funded on an ongoing basis following discussion and approval at the Oncoplastic MDT
- Patients whose oncoplastic surgery was initially in the private sector who are no longer able to receive treatment in the private sector will be allowed to access the pathway for management of significant complications and for completion of their reconstructive journey if this was not finished in the private sector.

For more information, please see https://remedy.bnssg.icb.nhs.uk/adults/breast/

BRAN

For any health- related decision, it is important to consider **"BRAN"** which stands for:

- **B**enefits
- **R**isks
- **A**lternatives
- Do **N**othing

Benefits

Reconstructive Breast surgery can:

- Reconstruct the breast mound to achieve an acceptable cosmetic outcome this has been shown to improve the patient's psychological wellbeing, self-esteem and confidence.

Risks

As with all types of surgery, there is a risk of developing certain complications.

Other complications can include:

- An adverse reaction to the anaesthetic
- Excessive bleeding
- Risk of infection
- Implant loss
- Flap loss
- Fat necrosis
- Implant rupture
- Implant displacement
- Capsular contracture
- Developing blood clots (where the blood thickens to form solid lumps)
- After breast surgery, all patients will have some degree of scarring

Alternatives

- Choosing to go flat after a mastectomy

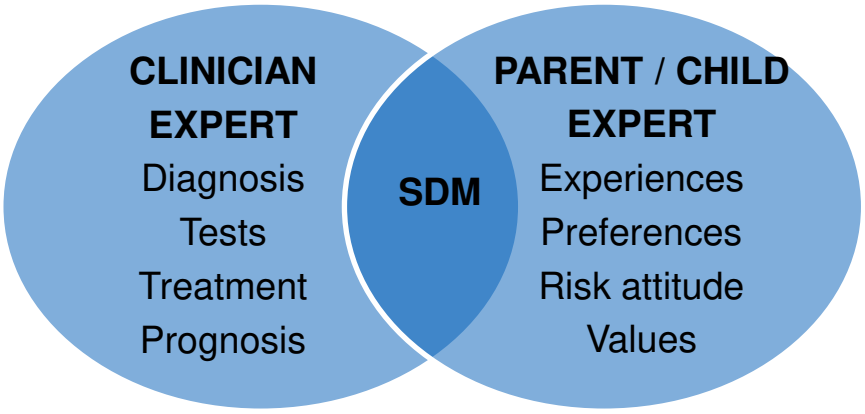
Do Nothing

- Choosing to go flat after a mastectomy

Shared Decision Making

If a person fulfils the criteria for breast surgery, it is important to have a partnership approach between the person and the clinician.

Shared Decision Making (SDM) is the meeting of minds of two types of experts:



It puts patients with breast cancer at the centre of decisions about their treatment and care. It respects what is unique about them including their preferences and values. It means that people receiving care and those involved in delivering care can understand what is important to the other person.

The patient and their clinician may find it helpful to use 'Ask 3 Questions:

1. What are the options?
2. What are the pros and cons of each option for **me**?
3. How do I get support to help me make a decision that is right for **me**?

Breast Reconstruction Post Cancer – Plain Language Summary

For most 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 or can be the full removal of a breast. These procedures are used to treat breast cancer in both females and males.

Following treatment for breast cancer, a patient may wish to recreate the appearance of having a breast so that they feel balanced and can dress as they would like. This can be achieved by wearing an external prosthesis (bra insert) and specialist bras. There are also several surgical options available for breast reconstruction after the removal of cancerous breast tissue. These include reconstruction using implants or the patient's own tissue. Breast reconstruction can be performed at the time of the removal of the breast (immediate reconstruction) or at a later date, dependant on patient's wishes and any additional cancer treatments that may be required.

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.

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 policy has been developed with the aid of the following references:

1. National Health Service (2021) Health A to Z: Mastectomy [online] www.nhs.uk/conditions
2. National Health Service (2019) Health A to Z: Cosmetic Surgery [online] www.nhs.uk/conditions
3. Cancer Research UK (2021) Breast Cancer [online] www.cancerresearchuk.org
4. Mayo Clinic (2021) Cosmetic Surgery Risks [online] www.mayoclinic.org
5. Breast Cancer Org (2021) Breast Reconstruction [online] www.breastcancer.org
6. Macmillan Cancer Support (2018) Cancer Information and Support www.macmillan.org.uk
7. NHS Information Centre (2010) National Breast Audit 2010 www.rcseng.ac.uk

Connected Policies

- Prophylactic Mastectomy
- Liposuction Treatment
- Skin Contouring Treatment
- Breast Surgery (Male)
- Cosmetic Surgery

Due regard

In carrying out their functions, the Bristol North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED), and NHSE Evidence-Based Interventions (EBI). This applies to all the activities for which the ICBs are responsible, including policy development and review.

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Document Control

Title of document:	Breast Reconstruction post-Cancer Policy
Authors job title(s):	Commissioning Policy Development Officer
Document version:	v2223.1.04
Supersedes:	v2122.1.03
Clinical Engagement received from:	NBT and UHBT
Discussion and Approval by Clinical Policy Review Group (CPRG):	24th January 2023
Discussion and Approval by ICB Commissioning Executive:	2nd March 2023
Date of Adoption:	TBA
Publication/issue date:	TBA
Review due date:	Earliest of either NICE publication or three years from approval.
Equality Impact Assessment Screening (date completed):	8th March 2022
Quality Impact Assessment Screening (date completed):	19th August 2022
Patient and Public Involvement	18th August 2022

OPCS Procedure codes

Must have any of (primary only):
B301,B302,B303,B304,B308,B309,B311,B312,B313,B314,B318,B319,B381,B382,B388,B389,B391,B392,B393,B394,B395,B398,B399,B351,B356,B358,B359

Relevant diagnoses for this policy:
ICD10 Code: None
Diagnoses for which the above procedures are permitted:
ICD10 Code: C50, C500, C509, C501, C502, C503, C504, C505, C506, C507, C508, C509D, Z853

Support

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on **BNSSG.customerservice@nhs.net.**

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

MRI Breast Screening

Criteria Based Access

All Patients

The ICB commissions MRI breast screening as laid out in NICE Clinical Guideline 164 and future versions of this guideline.

Note:

Any other requests outside of these guidelines must go through the exceptional funding panel.

For more information, please see https://remedy.bnssg.icb.nhs.uk/adults/breast/

BRAN

For any health- related decision, it is important to consider **"BRAN"** which stands for:

- **B**enefits
- **R**isks
- **A**lternatives
- Do **N**othing

Benefits

- Increased chance of detecting cancer early

Risks

- Bruising and swelling
- Allergic reaction

Alternatives

- Mammogram is to be used in conjunction with MRI

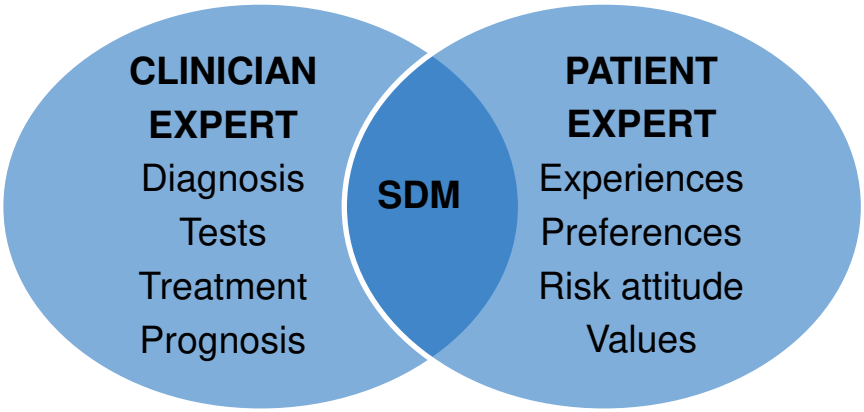
Do Nothing

Remember, you always have the option to do nothing. Doing nothing is an equally reasonable option to doing something. Sometimes “not yet” is a good enough answer until you gather more information.

Shared Decision Making

If a person fulfils the criteria for Prophylactic Mastectomy treatment, it is important to have a partnership approach between the person and the clinician.

Shared Decision Making (SDM) is the meeting of minds of two types of experts:



It puts people at the centre of decisions about their own treatment and care and respects what is unique about them. It means that people receiving care and clinicians delivering care can understand what is important to the other person.

The person and their clinician may find it helpful to use ‘Ask 3 Questions’:

1. What are my options? (see sections above)
2. What are the pros and cons of each option for **me**?
3. How do I get support to help me make a decision that is right for **me**?

Prophylactic Mastectomy – Plain Language Summary

This policy aims to allow women who are at a higher risk of developing cancer to access annual Magnetic Resonance Imaging [MRI] breast screening. An MRI is a scan that uses magnetic fields to produce detailed images of the body. MRI scans can last between 15 and 90 minutes depending on how many images are taken.

The TP53, BRCA1 and BRCA2 genes provide instructions for making tumour suppressing proteins that regulates cell division in a controlled way. Mutations of these genes can increase the risk of breast cancer.

Patients meeting the criteria listed below, based on age and estimated risk, should be offered Annual MRI scans of both breasts without further approval from the Commissioner.

This policy has been developed with the aid of the following:

1. National Health Service (2021) Health A to Z: When you'll be invited for breast screening and who should go [online] www.nhs.uk/conditions
2. NICE (2019) Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. (CG164) www.nice.org.uk

Connected Policies

Breast Reconstruction post-Cancer

Due regard

In carrying out their functions, the Bristol North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED), and NHSE Evidence-Based Interventions (EBI). This applies to all the activities for which the ICBs are responsible, including policy development and review.

Document Control

Title of document:	MRI Breast Screening
Authors job title(s):	Policy Development Support Officer
Document version:	v2223.1.2
Supersedes:	v1819.3.00
Clinical Engagement received from:	NBT and UHBW
Discussion and Approval by Commissioning Policy Review Group (CPRG):	24th January 2023
Discussion and Approval by ICB Commissioning Executive:	2nd March 2023
Date of Adoption:	
Publication/issue date:	
Review due date:	Earliest of either NICE publication or three years from approval.
Equality Impact Assessment Screening (date completed):	26th January 2023
Quality Impact Assessment Screening (date completed):	19th August 2022
Patient and Public Involvement	18th August 2022

OPCS Procedure codes

None coded diagnostic procedure.

Support

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NHS
Bristol, North Somerset and South Gloucestershire
Clinical Commissioning Group

Commissioning Policy

One-Step Nucleic Acid Amplification (OSNA) as an Intra-Operative Diagnostic Method for Detecting Metastasis in Breast Cancer

Criteria Based Access

Date Adopted: 13th October 2017
Version: 1819.2.00

Shaping better health

Document Control

Title of document:	One-Step Nucleic Acid Amplification [OSNA] as an Intra-Operative Diagnostic Method for Detecting Metastasis in Breast Cancer Policy
Authors job title(s):	IFR Manager
Document version:	1819.2.00
Supersedes:	1718.2.01
Clinical Approval – received from:	14 June 2017
Clinical Approval – date received:	CPRG
Discussion and Approval by Clinical Policy Review Group (CPRG):	14 June 2017
Discussion and Approval by CCG Commissioning Executive:	01 August 2017
Date of Adoption:	13 October 2017
Publication/issue date:	February 2019
Review due date:	Earliest of either NICE publication or three years from approval.
Equality Impact Assessment Screening (date completed):	In Development

Version Control

Version	Date	Reviewer	Comment
1718.2.01	27/03/2018	IFR Coordinator	Rebranded to BNSSG CCG
1819.2.00	26/10/2018	Commissioning Policy Development Support Officer	Smoking and BMI references updated, BNSSG branding refreshed, PALS update. Approved on 14th February 2019 by Commissioning Executive.

THIS IS A CRITERIA BASED ACCESS POLICY
TREATMENT MAY BE PROVIDED WHERE PATIENTS MEET THE CRITERIA BELOW

THIS POLICY RELATES TO ALL PATIENTS

One-Step Nucleic Acid Amplification (OSNA) as an Intra-Operative Diagnostic Method for Detecting Metastasis in Breast Cancer Policy

General Principles

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 CCG Exceptional Funding Request Panel.

1. Clinicians should assess the patients against the criteria within this policy prior to referring patients seeking treatment. Referring patients to secondary care that do not meet these criteria 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.
2. Patients will only meet the criteria within this policy where 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 and the EFR team should be approached for advice.
3. On limited occasions, the CCG may approve funding for a further assessment in secondary care 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 meets the criteria to access treatment in this policy.
4. Where funding approval is given by the Exceptional Funding Request Panel, it will be available for a specified period of time, normally one year.
5. 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).
6. Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing (ASH, 2016)
7. In applying this policy, all clinicians and those involved in making decisions affecting patient care will pay due regard to the need to eliminate unlawful discrimination,

harassment, victimisation, etc., and will advance equality of opportunity and foster good relations between people who share a protected characteristic and those who do not. In particular, due regard will be paid in relation to the following characteristics protected by the Equality Act 2010: age, disability, sex, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief and sexual orientation.

Background / Purpose and Scope

OSNA is a promising emerging technique as one of the sentinel node biopsy techniques and as such is still under evaluation. Its benefits are: identification of lymph node metastasis during the initial breast surgery and therefore enabling decision and undertaking of further lymph node resection (or not) during that initial surgery, avoiding thus the need for a second surgery and reducing the length of hospital stay. Current evidence identifies that the main uncertainty with OSNA is the potential over-diagnosis of breast cancer metastasis, i.e. higher proportion of micro-metastasis identified using OSNA than histopathology.

BNSSG CCGs have commissioned this technique since September 2010 in order to allow an Audit to consider its effectiveness. Overall the audit results show that the results are at large in coherence with published literature, e.g. comparable with the 4 centre British case study (2011). The results, therefore, do not raise any specific concerns with regards to the technique undertaken at UHB. The higher proportion of micrometastasis detected by OSNA as compared to histopathology is also not out of line with what is reported in the published literature.

It has however been agreed that a further period of commissioning to allow evaluation of the results should be undertaken.

POLICY CRITERIA – COMMISSIONED **CRITERIA BASED ACCESS**
OSNA is commissioned for all patients being surgically treated for breast cancer to allow evaluation of the diagnostic technique for a period of one year *until further evidence becomes available.*

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.

Individual cases will be reviewed at the CCG's Exceptional Funding Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on **BNSSG.customerservice@nhs.net .**

Connected Policies

N/A

This policy has been developed with the aid of the following references:

Ash. (2016). *Ash.org.uk.* Retrieved Sept 24, 2018, from www.ash.org.uk: www.ash.org.uk/briefings

Thelwall, S. P. (2015). 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, p. 1008.e1.

OPCS Procedure codes – For completion at a later date

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Risk Reducing Mastectomy

Criteria Based Access

All Patients

Before consideration of referral for management in secondary care, please review advice on the Remedy website (https://remedy.bnssg.icb.nhs.uk/adults/breast/) or consider use of advice and guidance services where available.

The ICB commissions Risk Reducing Mastectomy as laid out in NICE Clinical Guideline 164 and future versions of this guideline.

Note:

Any other requests outside of these guidelines must go through the exceptional funding panel.

For more information, please see https://remedy.bnssg.icb.nhs.uk/adults/breast/

BRAN

For any health- related decision, it is important to consider **"BRAN"** which stands for:

- **B**enefits
- **R**isks
- **A**lternatives
- Do **N**othing

Benefits

- Risk reducing mastectomy can **reduce the chances of developing breast cancer in women** at high risk of the disease

Risks

- Bleeding
- Infection
- Pain
- Anxiety or disappointment about changes to your appearance
- Complications arising from breast reconstruction

- The need for multiple operations.

Alternatives

- For women at high risk of breast cancer for any reason, routine screening starting at a young age can be an alternative to prophylactic mastectomy. Options include **clinical breast exams, mammograms, ultrasounds, and Magnetic Resonance Images [MRIs]**.

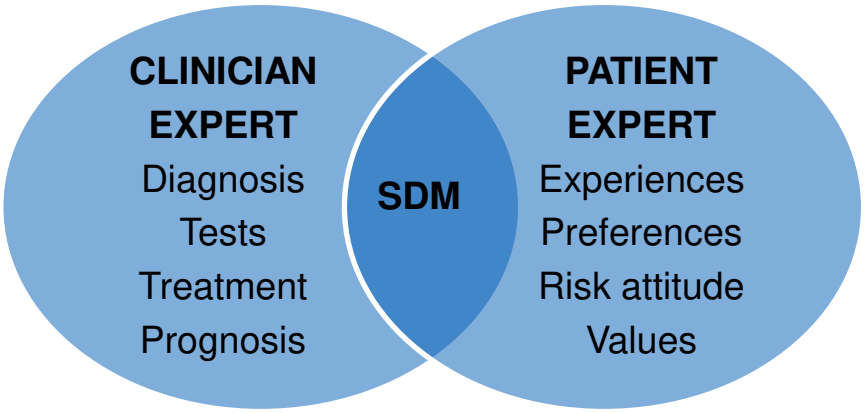
Do Nothing

Remember, you always have the option to do nothing. Doing nothing is an equally reasonable option to doing something. Sometimes “not yet” is a good enough answer until you gather more information.

Shared Decision Making

If a person fulfils the criteria for Prophylactic Mastectomy treatment, it is important to have a partnership approach between the person and the clinician.

Shared Decision Making (SDM) is the meeting of minds of two types of experts:



It puts people at the centre of decisions about their own treatment and care and respects what is unique about them. It means that people receiving care and clinicians delivering care can understand what is important to the other person.

The person and their clinician may find it helpful to use ‘Ask 3 Questions’:
1. What are my options? (see sections above)
2. What are the pros and cons of each option for **me**?
3. How do I get support to help me make a decision that is right for **me**?

Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Risk Reducing Mastectomy – Plain Language Summary

A Mastectomy is an operation to remove the breast. It is used to treat Breast Cancer in both men and women. It can also be used to reduce the risk of cancer developing in the breast. A risk reducing mastectomy is also known as a Prophylactic Mastectomy. These are carried out on healthy breasts to reduce the risk of Breast Cancer developing.

This procedure may be considered if a patient has a very high risk of developing breast cancer. This may be due to having a high family history of Breast Cancer. Genetic testing is offered to patients who are identified as having an increased likelihood of having one of these altered genes. Having an altered gene does not mean a patient develop Breast Cancer. If found, then a person is at a higher risk of developing Breast Cancer.

Prophylactic Mastectomies can reduce the risk of Breast Cancer by up to 90% in those who are high risk. In some cases, a lumpectomy – removing a lump from the breast – is all that may be required rather than removing the whole breast.

This policy has been developed with the aid of the following:

1. National Health Service (2021) Health A to Z: Mastectomy [online] www.nhs.uk/conditions
2. National Health Service (2019) Health A to Z: Prevention-Breast cancer in women [online] www.nhs.uk/conditions
3. NICE (2019) Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. (CG164) www.nice.org.uk
4. Breast Cancer Now Org (2021) Breast Cancer Advice and Support [online] www.breastcancernow.org

Other Reading for your Information

1. British Psychological Society (2020) Guidelines for the role of practitioner psychologists in the assessment and support of women considering risk-reducing breast surgery [online] www.bps.org.uk

Connected Policies

Breast Reconstruction post-Cancer

Due regard

In carrying out their functions, the Bristol North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED), and NHSE Evidence-Based Interventions (EBI). This applies to all the activities for which the ICBs are responsible, including policy development and review.

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Document Control

Title of document:	Prophylactic Mastectomy
Authors job title(s):	Policy Development Support Officer
Document version:	v2223.1.2
Supersedes:	v1819.2.00
Clinical Engagement received from:	NBT and UHBW Breast Teams
Discussion and Approval by Commissioning Policy Review Group (CPRG):	24th January 2023
Discussion and Approval by ICB Commissioning Executive:	2nd March 2023
Date of Adoption:	
Publication/issue date:	
Review due date:	Earliest of either NICE publication or three years from approval.
Equality Impact Assessment Screening (date completed):	20th December 2022
Quality Impact Assessment Screening (date completed):	19th August 2022
Patient and Public Involvement	18th August 2022

OPCS Procedure codes

All B27 codes, however this would not identify the specific groups which would require audit.

Support

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Equality Impact Assessment – Screening and Full Assessment

What are the main aims, purpose and outcomes of the review?	14.02.2022 - The purpose of this 3 year review is to explore if there is any new information which changes the CCG Commissioning stance.
Does this Review relate to a new or existing policy?	Existing
If existing, please provide more detail	14.02.2022 - The Female Breast surgery policy was clinically approved and adopted in June 2017. This was developed following a programme of work looking at reducing spend in areas considered to be cosmetic / low clinical value. NHS England have made reference to breast surgery for females in their Evidence Based Interventions programme. The information advises that they feel that Breast Reduction surgery (which falls within the scope of Breast Surgery policy) is subject to a restriction policy. This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate to not routinely fund this, and will remain an EFR policy, however it is appropriate to advise when removal of implants will be undertaken, this has been added to the policy. "Patients With Axillary Granulomas Patients who have had privately placed breast implants for cosmetic reasons that have ruptured and developed granulomas(usually axillary), are entitled to implant removal only. Removal of axillary granulomas is not routinely commissioned. **Complications Following Surgery for NHS commissioned breast reconstruction surgery non-cancer** Patients are entitled to access surgery following significant complications associated with their breast reconstruction. • Patients in whom further surgery for complications is considered **MUST** be discussed by the Oncoplastic MDT. The MDT must agree that the proposed surgery is appropriate and that the benefits outweigh the risks." This is likely to increase actvicty please see paper that Sarah Truelove has agreed for full details,
Outline the key decision that will be informed by this EIA	14.02.2022 - This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate and there are no changes to this policy.
Does this policy affect service users, employees and/or the wider community?	14.02.2022 - This does potentially affect all males within the system, as it prevents them from receiving elective surgery in secondary care.
Could the policy impact differently in relation to different characteristics protected by the Equality Act 2010?	14.02.2022 - It is not felt that this policy could impact differently in relation to different characteristis protected by the Equality Act 2010.
Age	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link this to any range.
Disability	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link this to any disabilty groups.
Gender Reassignment	Neutral
Please provide reasons for your answer and any mitigation required	14.02.2022 - There is no data available to link this to gender reassignment.
Race	Neutral
Please provide reasons for your answer and any mitigation required	There is no racial difference in the prevalence of ths.
Religion or Belief	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link this to any religion or belief.
Sex	Neutral
Please provide reasons for your answer and any mitigation required	14.02.2022 - Clinically this is a female only policy. A male policy also exists and this too restricts access to funding being secured via the EFR route. This ensures that Male / Females are treated equally in this manner.
Sexual Orientation	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link to sexual orientation.
Pregnancy and Maternity	Neutral

Please provide reasons for your answer and any mitigation required	There is no data available to link this to pregnancy and maternity..
Marriage & Civil Partnership	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link this to marriage and civil partnership..
Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010	Yes
Advance equality of opportunity between people who share a protected characteristic and those who do not	Yes
Foster good relations between people who share a protected characteristic and those who do not	Yes
Please provide reasons for your answer and any mitigation required	14.02.2022 - on review of the above charactistics it is felt that this review of " no change" will not affect the CCG's ability its statutory obligations under the public sector equality duties.
Does the policy relate to an area with known Health Inequalities? (If Answered YES - A full EIA is Required)	No
On the basis of this screening assessment do you consider this policy to be relevant to the General Duty or to any particular protected characteristic? (If Answered YES - A full EIA is Required)	No
If no, then explain your reasons and evidence Proceed to full EIA?	As above.
Proceed to full EIA?	No

EIA Impact Assessment Approver(s)

Name of EIA Approver	Sharon Woma
Comments from Equality Lead	Policy reviewed and EIA approved. IFR applied to policy for males, thus treatments appears equitable. Funding is based on meeting clinical criteria and should have no relevance to any protected characteristic. Providers will be aware of their Public Sector Equality Duty to ensure that patients do not experience discrimination, that equality of opportunity is advanced and foster relations between people who hold one protected characteristic and another. Monitoring will continue which should highlight any equality issues should they arise.
Date Approved	20/12/2022

Equality Impact Assessment – Screening and Full Assessment

What are the main aims, purpose and outcomes of the review?	01.12.2021 - The purpose of this 3 year review is to explore if there is any new information which changes the CCG Commissioning stance.
Does this Review relate to a new or existing policy?	Existing
If existing, please provide more detail	2.12.21 - A Male Breast surgery policy was clinically approved and adopted in June 2017. This was developed following a programme of work looking at reducing spend in areas considered to be cosmetic / low clinical value. NHS England have made reference to breast surgery for females in their Evidence Based Interventions programme. The information advises that they feel that Breast Surgery for males is not routinely commissioned. This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate and there are no changes to this policy. No changes have been made to this clinically approved policy.
Outline the key decision that will be informed by this EIA	02.12.2021 - This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate and there are no changes to this policy.
Does this policy affect service users, employees and/or the wider community?	02.12.2021 - This does potentially affect all males within the system, as it prevents them from receiving elective surgery in secondary care.
Could the policy impact differently in relation to different characteristics protected by the Equality Act 2010?	02.12.2021 - It is not felt that this policy could impact differently in relation to different characteristis protected by the Equality Act 2010.
Age	Negative
Please provide reasons for your answer and any mitigation required	This policy has a negative effect on males, in particular in certain age groups. **Newborn baby boys** Gynaecomastia can affect newborn baby boys, because oestrogen passes through the placenta from the mother to the baby. This is temporary and will disappear a few weeks after the baby is born. **Puberty** During puberty, boys' hormone levels vary. If the level of testosterone drops, oestrogen can cause breast tissue to grow. Many teenage boys have some degree of breast enlargement. Gynaecomastia at puberty usually clears up as boys get older and their hormone levels become more stable. **Older age** As men get older, they produce less testosterone. Older men also tend to have more body fat, and this can cause more oestrogen to be produced. These changes in hormone levels can lead to excess breast tissue growth. However this surgery is cosmetic and gives patients unnecessary surgical risks.
Disability	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link Gynecomastia to any disabilty groups.
Gender Reassignment	Neutral
Please provide reasons for your answer and any mitigation required	Transgender boys can experienced breast development while on testosterone, having been suppressed with a gonadotropin-releasing hormone (GnRH) agonist prior to testosterone therapy Pubertal gynecomastia is a common phenomenon in the cisgender male population. However, it has not been previously described in transgender boys. Transgender boys who undergo GnRH agonist treatment for puberty suppression and subsequently receive testosterone therapy for puberty induction may develop gynecomastia. Judicious adjustment of the testosterone therapy may lead to an improvement.
Race	Neutral
Please provide reasons for your answer and any mitigation required	There is no racial difference in the prevalence of gynecomastia.
Religion or Belief	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link this to any religion or belief.
Sex	Negative

Please provide reasons for your answer and any mitigation required	14.02.2022 - Clinically this is a male only policy. A female policy also exists and this too restricts access to funding being secured via the EFR route. This ensures that Male / Females are treated equally in this manner.
Sexual Orientation	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link to sexual orientation.
Pregnancy and Maternity	Neutral
Please provide reasons for your answer and any mitigation required	This is a male policy and does not affect females.
Marriage & Civil Partnership	Neutral
Please provide reasons for your answer and any mitigation required	There is no data available to link this to marriage and civil partnership.
Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010	Yes
Advance equality of opportunity between people who share a protected characteristic and those who do not	Yes
Foster good relations between people who share a protected characteristic and those who do not	Yes
Please provide reasons for your answer and any mitigation required	6.12.2021 - on review of the above charactistics it is felt that this review of " no change" will not affect the CCG's ability its statutory obligations under the public sector equality duties.
Does the policy relate to an area with known Health Inequalities? (If Answered YES - A full EIA is Required)	No
On the basis of this screening assessment do you consider this policy to be relevant to the General Duty or to any particular protected characteristic? (If Answered YES - A full EIA is Required)	No
If no, then explain your reasons and evidence Proceed to full EIA?	As above
Proceed to full EIA?	No

EIA Impact Assessment Approver(s)

Name of EIA Approver	Sharon Woma
Comments from Equality Lead	Policy reviewed and EIA approved. Male only policy, females have similar policy, suggesting equitable treatment. Funding is based on meeting clinical criteria and should have no relevance to any protected characteristic. Providers will be aware of their Public Sector Equality Duty to ensure that patients do not experience discrimination, that equality of opportunity is advanced and foster relations between people who hold one protected characteristic and another. Monitoring will continue which should highlight any equality issues should they arise.
Date Approved	20/12/2022

Equality Impact Assessment – Screening and Full Assessment

What are the main aims, purpose and outcomes of the review?	16.02.2022 - The purpose of this 3 year review is to explore if there is any new information which changes the CCG Commissioning stance.
Does this Review relate to a new or existing policy?	Existing
If existing, please provide more detail	16.02.2022 - Breast Reconstruction policy in place since 2018, the CPD team have worked with the systems Breast leads, including consultants at NBT and UHBW, to review this Criteria Based Access policy, to ensure that the policy remains clinically appropriate and follows all relevance guidance. The outcome of the review is that the policy remains robust and follows relevant guidance, however the team have expressed concerns around the fact that under the old policy there was a time restriction on continued support and surgeries for patients that continue to have problems following surgery given by the NHS, we have worked with the team to understand this issue and have adjusted the policy to now allow this as long as it is following agreement from an oncoplastic MDT. Also the team expressed concerns about not being able to treat patients that had complications following treatment in the private sector, this has also been addressed so that appropriate treatment can be carried out to help patients that have had issues with surgeries in the private sector but are unable to go back to the treatment centre, this would be limited by removing problematic implants but not replacing them.
Outline the key decision that will be informed by this EIA	16.02.2022 - This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate some minor changes to this policy.
Does this policy affect service users, employees and/or the wider community?	16.02.2022 - This policy affects every female in the system.
Could the policy impact differently in relation to different characteristics protected by the Equality Act 2010?	16.02.2022 - It is not felt that this policy could impact differently in relation to different characteristis protected by the Equality Act 2010.
Age	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - The age range according to studies is between 70 - 95, but affects all age ranges. Breast cancer surgery in older women: outcomes of the Bridging Age Gap in Breast Cancer study - Morgan - 2020 - BJS (British Journal of Surgery) - Wiley Online Library
Disability	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - There is no data available to link this to any disabilty groups.
Gender Reassignment	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - There is no data available to link this to gender reassignment.
Race	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - White women are slightly more likely to be affected by this policy, but it affects all racial classes. Breast Cancer Risk Factors: Race/Ethnicity
Religion or Belief	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - There is no data available to link this to any religion or belief.
Sex	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - This can affect all users that are affected by breast cancer.
Sexual Orientation	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - There is no data available to link to sexual orientation.
Pregnancy and Maternity	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - There is no data available to link this to pregnancy and maternity..
Marriage & Civil Partnership	Neutral
Please provide reasons for your answer and any mitigation required	16.02.2022 - There is no data available to link this to marriage and civil partnership.
Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010	Yes
Advance equality of opportunity between people who share a protected characteristic and those who do not	Yes

Foster good relations between people who share a protected characteristic and those who do not	Yes
Please provide reasons for your answer and any mitigation required	16.02.2022 - on review of the above charactistics it is felt that this review of " no change" will not affect the CCG's ability its statutory obligations under the public sector equality duties.
Does the policy relate to an area with known Health Inequalities? (If Answered YES - A full EIA is Required)	No
On the basis of this screening assessment do you consider this policy to be relevant to the General Duty or to any particular protected characteristic? (If Answered YES - A full EIA is Required)	No
If no, then explain your reasons and evidence Proceed to full EIA?	As above.
Proceed to full EIA?	No

EIA Impact Assessment Approver(s)

Name of EIA Approver	Sharon Woma
Comments from Equality Lead	On basis this is administrative and no change to policy/and the EIA is not due for review- I am satisfied that the policy has been successfully equality impact analysed. There is no requirement for a Full Equality Impact Assessment.
Date Approved	08/03/2022

Equality Impact Assessment – Screening and Full Assessment

What are the main aims, purpose and outcomes of the review?	21.02.2022 - The purpose of this 3 year review is to explore if there is any new information which changes the CCG Commissioning stance.
Does this Review relate to a new or existing policy?	Existing
If existing, please provide more detail	21.02.2022 - This policy was clinically approved and adopted in April 2019. This was developed to ensure alignment of the NICE guidelines. This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate but the following was required: BNSSG's Business Intelligence (BI) data indicates that in 2021/22, 32 women were funded for Breast Surgery at a total cost of £127,450. According to BI data, for 2021/2022 43 patients underwent breast surgery for axillary lymph node procedures. These related to axillary granulomas causing significant issues (removal of the implants without replacement stops any further progression to axilla.) The overall cost was £80,231. Some of the procedures undertaken are not routinely funded under the current commissioning policy. However, from the available data it is unclear how many of these patients would have received funding for this treatment under the current commissioning policies for Breast Surgery. Under the current policy Breast reconstruction is only commissioned along the cancer pathway, to a maximum of three procedures in a two year reconstruction window. Breast reconstruction is not commissioned for asymmetry nor for breast absence. Where patients have previously had a reconstruction on the NHS, both cancer and non-cancer pathways, no further remedial surgery is commissioned following the initial treatment. This includes breast implant capsule formation, ruptures or leakage to axilla. • Other procedures not commissioned include • Breast reduction surgery • Gynaecomastia surgery • Prophylactic mastectomy outside of NICE guidance • Surgery where a patient has privately had breast implant surgery When considering national guidance, looking at complaints, MP letters and in discussion with the local oncoplastic breast surgical team the ICB's stance around breast reduction, gynaecomastia and prophylactic mastectomy outside of NICE guidance is supported. Where patients have privately had breast implant surgery this is largely in line with two exceptions: • Patients who had reconstruction privately for breast cancer but who no longer have insurance cover (Equity). • Patients who have leakage from breast implants that have been inserted privately, often for cosmetic reasons, but where there is leakage causing granulomas to form in the axilla. (Patients end up being seen regularly in NHS 2WW clinics and breast implant removal alone is cost effective). Where the ICB is not in line is around the ongoing care of patients who have had reconstruction under the NHS and where further surgery is needed to maintain the benefits of the initial surgery. In discussion with the oncoplastic team there is no desire to provide perfection but to maintain a reasonable level of care. In order to ensure this all decisions are at present, and will continue to be in the future, considered and advised by the Oncoplastic Multi-disciplinary Team. **Proposed Changes** • Patients who have had breast reconstruction surgery are able to access long term support and surgical intervention for the reasonable ongoing support of the reconstruction surgery including implant removal and replacement or transition to the most appropriate reconstruction where required. • Patients who have had implants not under the NHS who have developed leakage and granulomas have formed, usually in the axilla can have implant removal but not replacement under the NHS • Patients who have had a reconstruction following breast cancer privately but who are no longer covered in the private sector will be supported in an ongoing manner as if their surgery was initially performed in the NHS All surgery for these patients should be agreed using the Oncoplastic MDT to ensure that the surgery is appropriate, proportionate and fits within the policy in place at the time
Outline the key decision that will be informed by this EIA	21.02.2022 - This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate and there are no changes to this policy.
Does this policy affect service users, employees and/or the wider community?	21.02.2022 - This does potentially affect all patients within the system, as it prevents them from receiving elective treatment in secondary care, albeit in line with NICEguidelines.
Could the policy impact differently in relation to different characteristics protected by the Equality Act 2010?	21.02.2022 - It is not felt that this policy could impact differently in relation to different characteristis protected by the Equality Act 2010.
Age	Neutral

Please provide reasons for your answer and any mitigation required	UK guidelines recommend that women with a moderate or high risk of breast cancer because of their family history should start having screening mammograms every year in their forties. If you are younger than 40 and have an increased risk of breast cancer, you should be offered yearly MRI scans from the age of **30 or 40**. So the policy affects this age range more than other ages, but does cover all ages.
Disability	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to any disabilty groups.
Gender Reassignment	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to gender reassignment.
Race	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to any race.
Religion or Belief	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to any religion or belief.
Sex	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to any sex, however less than 1% of breast cancer cases are male. Mammograms are not routinely offered to men and may be difficult to perform if there is a small amount of breast tissue. A doctor may recommend screening mammography for men with a genetic mutation that increases the risk of developing the disease.
Sexual Orientation	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to any sexual orientation.
Pregnancy and Maternity	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to pregnancy and maternity. inding Breast Cancer During Pregnancy
Marriage & Civil Partnership	Neutral
Please provide reasons for your answer and any mitigation required	21.02.2022 - There is no data available to link breast screening to marriage and civil partnership.
Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010	Yes
Advance equality of opportunity between people who share a protected characteristic and those who do not	Yes
Foster good relations between people who share a protected characteristic and those who do not	Yes
Please provide reasons for your answer and any mitigation required	21.02.2022 - on review of the above characteristics it is felt that this review and its proposed changes for this policy will make it more equitable will not affect the CCG's ability its statutory obligations under the public sector equality duties.
Does the policy relate to an area with known Health Inequalities? (If Answered YES - A full EIA is Required)	No
On the basis of this screening assessment do you consider this policy to be relevant to the General Duty or to any particular protected characteristic? (If Answered YES - A full EIA is Required)	No
If no, then explain your reasons and evidence Proceed to full EIA?	As above.
Proceed to full EIA?	No

EIA Impact Assessment Approver(s)

Name of EIA Approver	Halle Fowler
Comments from Equality Lead	Happy to approve this EIA on the basis that it is unlikely that the proposed changes would negatively impact a person with a protected characteristic. Where age or gender may be a consideration this has been discussed and an appropriate conclusion found that the changes to this policy should not impact negatively.

Date Approved	26/01/2023

Equality Impact Assessment – Screening and Full Assessment

What are the main aims, purpose and outcomes of the review?	22.02.2022 - The purpose of this 3 year review is to explore if there is any new information which changes the CCG Commissioning stance.
Does this Review relate to a new or existing policy?	Existing
If existing, please provide more detail	22.02.2022 - This policy was clinically approved and adopted in April 2019. This was developed to ensure alignment of the NICE guidelines. A mastectomy is an operation to remove a breast or breasts. It is usually carried out to treat breast cancer. In some people it is considered as a preventative option to remove the breast(s) to remove the risk of cancer. This policy confirms that patients who are identified as having a high risk of developing breast cancer are eligible to access a prophylactic mastectomy without the need to secure additional funding. This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate and there are no changes to this policy. No changes have been made to this clinically approved policy.
Outline the key decision that will be informed by this EIA	22.02.2022 - This 3 year review with clinicians at North Bristol Trust and University Hospitals Trust Bristol & Weston has concluded that this is still appropriate and there are no changes to this policy.
Does this policy affect service users, employees and/or the wider community?	22.02.2022 - This does potentially affect all patients within the system, as it prevents them from receiving elective treatment in secondary care, albeit in line with NICE guidelines.
Could the policy impact differently in relation to different characteristics protected by the Equality Act 2010?	22.02.2022 - It is not felt that this policy could impact differently in relation to different characteristis protected by the Equality Act 2010.
Age	Neutral
Please provide reasons for your answer and any mitigation required	This policy covers all age ranges following NICE guidelines. Recommendations | Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer | Guidance | NICE
Disability	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to link this policy to any disabilty groups.
Gender Reassignment	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to link this policy to gender reassignment.
Race	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to link this policy to any race.
Religion or Belief	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to linkthis policy to any religion or belief.
Sex	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to link this policy to any sex.
Sexual Orientation	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to link breast screening to any sexual orientation.
Pregnancy and Maternity	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to link this policy to pregnancy and maternity.
Marriage & Civil Partnership	Neutral
Please provide reasons for your answer and any mitigation required	22.02.2022 - There is no data available to link this policy to marriage and civil partnership.
Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Equality Act 2010	Yes
Advance equality of opportunity between people who share a protected characteristic and those who do not	Yes
Foster good relations between people who share a protected characteristic and those who do not	Yes

Please provide reasons for your answer and any mitigation required	22.02.2022 - on review of the above charactistics it is felt that this review of " no change" will not affect the ICB's ability its statutory obligations under the public sector equality duties.
Does the policy relate to an area with known Health Inequalities? (If Answered YES - A full EIA is Required)	No
On the basis of this screening assessment do you consider this policy to be relevant to the General Duty or to any particular protected characteristic? (If Answered YES - A full EIA is Required)	No
If no, then explain your reasons and evidence Proceed to full EIA?	As above.
Proceed to full EIA?	No

EIA Impact Assessment Approver(s)

Name of EIA Approver	Sharon Woma
Comments from Equality Lead	Policy reviewed and EIA approved. Funding is based on meeting clinical criteria and should have no relevance to any protected characteristic and applications are reviewed by Individual Funding Panel. Providers will be aware of their Public Sector Equality Duty to ensure that patients do not experience discrimination, that equality of opportunity is advanced and foster relations between people who hold one protected characteristic and another. Monitoring will continue which should highlight any equality issues should they arise.
Date Approved	20/12/2022