

PARTIALLY EXCLUDED POLICY – PE114 SURGERY TO REMOVE OR REPLACE BREAST IMPLANTS

Policy author: Ipswich and East Suffolk Clinical Commissioning Group and West Suffolk Clinical Commissioning Group supported by Public Health Suffolk, Suffolk County Council

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Review date: February 2020

1. Policy Summary

- 1.1 The Cosmetic and Lifestyle Procedure Surgery for removal or replacement of breast implants is considered a low priority procedure and should not be commissioned. Funding requests are considered by the Suffolk CCG's Individual Funding Request (IFR) Panel if there are exceptional circumstances i.e. there is something about the patient's condition or circumstances that differentiate them on the basis of need from other patients with a similar diagnosis or condition and would justify funding being provided in an individual case when it is not routinely funded for others.
- 1.2 This partially excluded policy offers some guidance to the referring clinician and the IFR Panel when considering such requests. It must be clarified these are NOT referral criteria, and only supporting guidance for the IFR panel.

2. Background to the Procedure

- 2.1 Breast implants are used both for cosmetic breast augmentation procedures and also in breast reconstruction surgery in the context of breast cancer or following prophylactic mastectomy. Breast implants can cause a number of complications, including capsular contracture, infection and rupture of the implant. Breast implants do not last a patient's lifetime and further surgery is often requested either due to problems with the implants or due to changes in the breasts around the implants.

3. Rationale Behind Policy Decision

- 3.1 Breast implant removal or replacement surgery is a cosmetic surgical procedure. Cosmetic surgery is defined as "the choice to undergo an operation, or invasive medical procedure, to alter one's physical appearance for aesthetic (visual) rather than medical reasons." Breast implant (breast augmentation) surgery is not routinely available on the NHS and is most often carried out privately. For cosmetic intention it is not routinely funded by the clinical commissioning group.

4. Guidance to IFR Panel

- 4.1 Breast implant removal or replacement for the sole purpose of changing the cosmetic appearance of the breast should not be funded.
- 4.2 Patients who have had implants inserted privately should be directed back to the private provider in the first instance. Please refer to the CCG policy on “Boundaries between NHS & private care”.
- 4.3 Exceptional case funding for breast implant removal may be considered where there is a clear clinical need with examples of these situations listed below AND where specialist clinical opinion is that the benefit of the procedure outweighs the risk of harm.
- a) Pain due to capsular contracture grade III/IV on Baker classification*
 - b) Silicon implant leakage or rupture
 - c) Implants complicated by recurrent infection
 - d) Breast disease
 - e) New national guidance is issued relating to removal of specific implants
- 4.4 *Baker classification system:^{3,4}
- I breast that looks and feels absolutely natural
 - II breast with minimal contracture in that the surgeon can tell surgery has been performed but there are no symptoms
 - III moderate contracture with some firmness felt by the patient
 - IV severe contracture, which is obvious from observation and symptomatic in the patient.
- 4.5 For patients where funding for removal is approved it is advised that the CCG only commission the replacement of implants at the time of breast implant removal if the original procedure was funded by the NHS AND the patient remains eligible for breast augmentation in accordance with the CCG's current policies.
- 4.6 Below is the general guidance relating to surgical breast procedures that is included in all breast surgery policies. It has been included in this policy for consistency but may be less relevant as the clinical indications (as stated above) for implant removal/replacement may be more urgent. For example, in the case of a leaking or ruptured implant we would not expect the patient to maintain a BMI below 30kg/m² for a year prior to this being removed. The panel are advised to use their best judgement in determining the relevance of each piece of guidance. We would continue to recommend smoking cessation as detailed.

4.7 General guidance relating to surgical breast procedures to be taken into account where applicable:

- a) Patients receiving treatment for breast cancer as part of the breast cancer treatment pathway should be offered reconstruction surgery in line with NICE CG80 and this is not covered by this policy.
- b) Although the development of the breast in women is likely to be completed by the age of 18, the request will only be considered in women aged 21 and over as this will allow time for them to receive the necessary support and counselling to arrive at an informed decision.
- c) The panel also need to take into account the impact on the changes in the breast of any likely pregnancy and breast feeding.
- d) BMI must be stable and sustained below 30kg/m² for at least 1 year prior to referral with documentation of BMI in the clinical records and provided to the panel at a minimum of 0, 6 and 12 months.
- e) Wherever possible anonymised clinical photographs would help the panel when considering the submission however this is not a mandatory requirement.
- f) Wherever clinically appropriate a referral to physiotherapy should be considered and a detailed physiotherapy report to be enclosed with the submission.
- g) Where patients are suffering psychologically, appropriate referrals should have been made and other potential causes of psychological distress been appropriately evaluated and treated before referral for consideration of cosmetic surgery is made.
- h) Documentation of mental health such as HAD score or PHQ-9 should also be enclosed.

4.8 Smoking status:

- a) Stipulate that patients undergoing this operation who smoke must cease smoking 3-4 weeks prior to surgery at their pre-operative consultation and urge that they continue to abstain from all forms of smoking for 3-4 weeks during the post-operative phase. Advise the patient that use of electronic nicotine delivery systems and other forms of nicotine (i.e. patch, gum) will show positive cotinine levels in their saliva and may trigger a positive test result when checked. AND
- b) Encourage the patient to complete a smoking cessation course with the local commissioned smoking cessation provider prior to their operation to help their abstinence. AND
- c) Stipulate that the patient undertakes a cotinine test that demonstrates the patient is not smoking within the 4 week window prior to their surgery (cotinine level >10 ng/mL indicates that the patient is smoking).

4.9 Advise the patient that failure to comply with these criteria will lead to their surgery being cancelled.

5. References

1. Rocco N, Rispoli C, Moja L, Amato B, Iannone L, Testa S, Spano A, Catanuto G, Accurso A, Nava MB. Different types of implants for reconstructive breast surgery. *Cochrane Database of Systematic Reviews* 2016, *Issue 5*. Art. No.: *CD010895*. DOI: *10.1002/14651858.CD010895.pub2*.
2. NHS Choices <http://www.nhs.uk/conditions/cosmetic-treatments-guide/Pages/breast-enlargement.aspx>
3. Spear SL, Baker JL., Jr Classification of capsular contracture after prosthetic breast reconstruction. *Plast Reconstr Surg*. 1995;96:1119–1123
4. Headon H, Kasem A, Mokbel K. Capsular Contracture after Breast Augmentation: An Update for Clinical Practice. *Archives of Plastic Surgery*. 2015;42(5):532-543. doi:10.5999/aps.2015.42.5.532.
5. NHS Digital Breast and Cosmetic Implant Registry (BCIR) <http://content.digital.nhs.uk/bcir>
6. NHS Modernisation Agency Action on Cosmetic Surgery www.bapras.org.uk/.../information-for-commissioners-of-plastic-surgery-services.pdf
7. Lancashire North CCG <http://www.lancashirenorthccg.nhs.uk/download/governing-body-papers/Agenda%20Item%2010.5.%20Commissioning%20Policy%20for%20Breast%20Implant%20Removal%20and%20Replacement.pdf>.
8. Devon CCG <https://northeast.devonformularyguidance.nhs.uk/referral-guidance/commissioning-policies/breast-implants---removal-and-replacement>
9. NHS Kernow CCG <http://policies.kernowccg.nhs.uk/DocumentsLibrary/KernowCCG/IndividualFundingRequests/Policies/RemovalAndReplacementBreastImplantsPolicy.pdf>
10. Gloucestershire CCG www.gloucestershireccg.nhs.uk/.../Removal-and-replacement-of-breast-implants.doc

East Midlands commissioning policy for cosmetic procedures
www.southernderbyshireccg.nhs.uk/EasySiteWeb/GatewayLink.aspx%3FallId%3D3284+&cd=8&hl=en&ct=clnk&gl=uk