

Policy for Breast Implant Removal and Replacement

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Version:	1.1
Purpose	<p>This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.</p> <p>This policy is based on the ICB's Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).</p>
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Author (inc Job Title):	
Ratified by: (Name of responsible Committee)	LSCICB Board (adopted 1 July 2022)
Cross reference to other Policies/Guidance	
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Target audience:	All LSCICB Staff

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Document control:		
Date:	Version Number:	Section and Description of Change
March 2020	V1.0	<p>Policy ratified by Healthier Lancashire and South Cumbria's Joint Committee of Clinical Commissioning Groups (JCCCGs).</p> <p>Breast Implant Removal and Replacement procedure section removed from the Cosmetic Procedures and placed in a separate standalone policy document.</p> <p>Policy revised by removing the following statement from Breast implant replacement:</p> <p><i>'AND c) the replacement can be carried out as part of the same procedure as the removal of the previous implant.'</i></p>
July 2022	V1.1	Policy adopted by Lancashire and South Cumbria ICB – references to CCG replaced by ICB where relevant

1. Policy

- 1.1 The ICB will not routinely commission any treatments or procedures that have the primary purpose of changing the appearance of a part of the body.
- 1.2 The following procedures have been categorised as either 'not routinely funded' or 'restricted'. An explanation of these definitions are as follows:
- 1.3 Not routinely funded: These treatments are considered to be cosmetic and will only be provided if funding is approved on an exceptional case basis following the submission of an Individual Funding Request (IFR).
- 1.4 Restricted: The ICB will fund these treatments/procedures to treat the conditions set out below, provided the patient meets the intervention specific policy criteria at sections 2 and 3. In all other circumstances these interventions are considered to be cosmetic.

2. Breast implant removal: Restricted

- 2.1 The ICB will commission the removal of breast implants under the following circumstances:
 - a. the implant was manufactured by Poly Implant Prothese (PIP) between 2001 and 2010 and the requirements of any relevant Department of Health guidance in force at the time of the request are met.

OR
 - b. there is evidence that the implants have ruptured

OR
 - c. there is evidence of capsular contracture, and the patient is experiencing significant pain.

OR
 - d. there is evidence, not available at the time of the implantation, that there is an increased risk of developing breast cancer (either as a result of an emerging family history, or as a result of a malignant diagnosis in the contralateral breast) and the implant is impairing mammography.

OR
 - e. the contralateral breast implant satisfies one of the above criteria, is being removed, and the patient is requesting bilateral removal.

3. Breast implant replacement: Restricted

- 3.1 The ICB will commission the supply and insertion of a replacement breast implant under the following circumstances:

- a. the original implant was supplied and inserted by the NHS

AND

- b. the removal of the implant is in accordance with this policy

3.2 When the ICB funds a replacement implant it is the expectation that the surgeon will explain the implications and risks in relation to breast screening and clinical detection of breast cancer and will record in the notes that the patient is aware of such risks and takes responsibility for them.

4. Scope and definitions

4.1 Requests to address the following issues, irrespective of gender or age, are within the scope of this policy:

- Problems with breast implants
- Other conditions that the ICB considers to be equivalent to the above.

4.2 The ICB recognises that a patient may have a concern about their appearance, which may or may not be caused by or amount to a medical condition and they may wish to have a service provided to improve their appearance. The ICB also recognises that they may be distressed by their appearance and by the fact that they may not meet the criteria specified in this commissioning policy.

4.3 Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.

4.4 For the purpose of this policy the ICB defines:

- "Pathology" (adjective "pathological") is defined as a biologically based health problem which, in a cosmetic context, is likely to be caused by a congenital (including genetic) anomaly, infection or inflammation, trauma, neoplasia, or premature degeneration.

4.5 The ICB is committed to eliminating discrimination and promoting equality in its own policies, practices, and procedures. While no protected characteristic under the Equality Act is automatically a matter for exceptionality under this policy, the ICB is committed to treating everyone equally and with the same attention, courtesy and respect regardless of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation.

5. Appropriate Healthcare

5.1 Some requests for cosmetic procedures arise from an appearance which is not pathological. Such procedures do not have the intended outcome of preventing, diagnosing or treating a medical condition (paragraph 3.3a of the Statement of Principles). Therefore, such requests do not accord with the Principle of Appropriateness.

- 5.2 Some requests for cosmetic procedures arise from an appearance which, although related to pathology, is causing no significant symptoms apart from the appearance and the distress resulting from that appearance. A substantial number of people in the population will have these features.
- 5.3 The ICB considers other services competing for the same ICB resource more clearly have a purpose of preserving life or of preventing grave health consequences (paragraph 3.4(f) of the Statement of Principles). The ICB also considers that the use of healthcare for the problem in question would amount to excessive medicalisation (paragraph 3.4(g) of the Statement of Principles).
- 5.4 Therefore, such requests do not accord with the Principle of Appropriateness.

6. Effective Healthcare

- 6.1 The ICB does not call into question the effectiveness of cosmetic procedures and therefore this policy does not rely on the Principle of Effectiveness.
- 6.2 Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects before confirming a decision to provide funding.

7. Cost Effectiveness

- 7.1 The ICB does not call into question the cost-effectiveness of cosmetic procedures and therefore this policy does not rely on the Principle of Cost-Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the treatment is likely to be Cost Effective in this patient before confirming a decision to provide funding.

8. Ethics

- 8.1 The ICB does not call into question the ethics of cosmetic procedures and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.

9. Affordability

- 9.1 The ICB has a limited budget and must make difficult choices. As a result of the need to manage resources within budget, the Principle of Affordability is a basis for making restrictions to the commissioning of cosmetic healthcare.

10. Exceptions

- 10.1 The ICB will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.

10.2 In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this ICB. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.

11. Force

11.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.

11.2 In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then:

- If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory.
- If the new NICE guidance does not have mandatory status, then the ICB will aspire to review and update this policy accordingly. However, until the ICB adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this ICB are concerned.

12. References

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