

# Clinical Commissioning Policy

## Nipple inversion, surgical correction

Category 1 Intervention - Not routinely commissioned -

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Purpose	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.
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## 1. Introduction

- 1.1 This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.
- 1.2 This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document but should be considered alongside all the other policies in the suite as well as the core principles outlined in Appendix 1.
- 1.3 At the time of publication, the evidence presented per procedure/treatment was the most current available.

## 2. Purpose

- 2.1 This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

## 3. Policy statement

- 3.1 Nipple inversion may be indicative of breast cancer which should always be excluded.
- 3.2 Most cases can be managed by use of a suction device for 3 months.
- 3.3 Otherwise, surgical correction of nipple inversion is not routinely commissioned.

## 4. Exclusions

- 4.1 This policy excludes all referrals where malignancy is suspected.

## 5. Rationale

- 5.1 It is generally accepted that the majority of cases of nipple inversion will respond to an appropriately used suction device without the need for surgery.

## 6. Underpinning evidence

- 6.1 The inverted nipple is a frequently encountered problem which can cause difficulties with breastfeeding, sexuality and aesthetic dissatisfaction.<sup>1</sup> It can occur as a result of an underlying breast malignancy which should always be ruled out.<sup>2</sup> Apart from nipple inversion, the symptoms of inflammatory breast cancer include erythema, skin changes, oedema and warmth of the affected breast.<sup>3</sup>
- 6.2 The prevalence has been cited as occurring in 2% – 10% of women<sup>4-6</sup> but in a prospective cross-sectional study (2021) using Internet crowdsourcing, of the 398 women interviewed, 71/398 (17.8%) had nipple inversion.<sup>5</sup> In a larger survey of 1625 women aged between 19 – 26 years, the condition was present bilaterally in 87% of the 53 women who presented with this malformation.<sup>6</sup>

- 6.3 In 1999, Sakai proposed a scheme to classify the degree of the deformity.<sup>7</sup> Grade I is where the inversion can be corrected by simple manipulation, grade II is an inversion which can be corrected by manipulation but frequently re-occurs and grade III (the most severe) are inversions which can't be corrected by manipulation unless a surgical procedure is performed.
- 6.4 The available surgical techniques are divided into those which are lactiferous duct preserving and those which are lactiferous duct damaging (i.e. prone to affect breastfeeding).<sup>1,8</sup> Multiple techniques have been developed to correct the inverted nipple but no single procedure is universally applicable for correction of all types of inverted nipple.<sup>9</sup> A large systematic review (2020) concluded it was difficult to state which was the best surgical strategy to adopt to obtain satisfactory and stable results with minimal morbidity.<sup>4</sup> However, the same review showed that satisfactory correction can be obtained in 89% of cases with a recurrence rate of 3.89%.
- 6.5 There is very little (if any) national guidance on the management of inverted nipple. A very recent review (2021) commented there is no defined pathway for these patients.<sup>10</sup> However, the NHS modernisation agency in its "Action on plastic surgery" document (2005) recommended that surgical correction of nipple inversion should only be available for functional reasons in a post pubertal woman and if the inversion hasn't been corrected by use of a non-invasive suction device.<sup>2</sup> Idiopathic nipple inversion can often be corrected by the application of sustained suction (used correctly for up to 3 months).
- 6.6 It is concluded that nipple inversion is very common and once breast malignancy has been ruled out can be conservatively managed (using a suction device) in the vast majority of cases.

## REFERENCES

1. Hernandez Yenty QM, Jurgens WJFM, van Zuijlen PPM, et al. Treatment of the benign inverted nipple: A systematic review and recommendations for future therapy. *Breast (Edinburgh, Scotland)* 2016;**29**:82-89. doi: 10.1016/j.breast.2016.07.011
2. Information for commissioners of plastic surgery services: Referrals and guidelines in plastic surgery. Action on plastic surgery. London: NHS modernisation agency, 2005:24.
3. Hester RH, Hortobagyi GN, Lim B. Inflammatory breast cancer: early recognition and diagnosis is critical. *American journal of obstetrics and gynecology* 2021 doi: 10.1016/j.ajog.2021.04.217
4. Mangialardi ML, Baldelli I, Salgarello M, et al. Surgical Correction of Inverted Nipples. *Plastic and reconstructive surgery Global open* 2020;**8**(7):e2971. doi: 10.1097/GOX.0000000000002971
5. Stone G, Shauly O, Gould DJ. Crowdsourcing the Public's Perception and Systematic Review of Nipple Inversion and Its Repair. *Journal of women's health* 2021 doi: 10.1089/jwh.2020.8953
6. Park HS, Yoon CH, Kim HJ. The prevalence of congenital inverted nipple. *Aesthetic plastic surgery* 1999;**23**(2):144-46.
7. Sakai S, Sakai Y, Izawa H. A new surgical procedure for the very severe inverted nipple. *Aesthetic plastic surgery* 1999;**23**(2):139-43.
8. Yukun L, Ke G, Jiaming S. Application of Nipple Retractor for Correction of Nipple Inversion: A 10-Year Experience. *Aesthetic plastic surgery* 2016;**40**(5):707-15. doi: 10.1007/s00266-016-0675-0
9. Lee MJ, Depoli PA, Casas LA. Aesthetic and predictable correction of the inverted nipple. *Aesthetic surgery journal* 2003;**23**(5):353-56. doi: 10.1016/S1090-820X(03)00209-7
10. Olivas-Menayo J, Berniz C. Inverted Nipple Correction Techniques: An Algorithm Based on Scientific Evidence, Patients' Expectations and Potential Complications. *Aesthetic plastic surgery* 2021;**45**(2):472-80. doi: 10.1007/s00266-020-01909-6

## 7. Force

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

## 8. Coding

- 8.1 **Office of Population Censuses and Surveys (OPCS)**  
B35.6 Eversion of nipple
- 8.2 **International classification of diseases (ICD-10)**  
None

## 9. Monitoring And Review

- 9.1 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
  - Post activity monitoring through routine data
  - Post activity monitoring through case note audits
- 9.2 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

## 10. Quality and Equality Analysis

- 10.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

# Appendix 1 - Core Objectives and Principles

## Objectives

The main objective for having healthcare commissioning policies is to ensure that:

- Patients receive appropriate health treatments
- Treatments with no or a very limited evidence base are not used; and
- Treatments with minimal health gain are restricted.

## Principles

This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

- Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
- Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
- Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
- Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
- Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
- Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the 'NHS Choice' framework.
- Commissioning decisions will give 'due regard' to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

## Core Eligibility Criteria

There are a number of circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for the procedures and treatments listed, regardless of whether they meet the criteria; or the procedure or treatment is not routinely commissioned.

These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
- NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients wishing to undergo Gender reassignment, this is the responsibility of NHS England and patients should be referred to a Gender Identity Clinic (GIC) as outlined in the Interim NHS England Gender Dysphoria Protocol and Guideline 2013/14.

## Cosmetic Surgery

Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

A summary of Cosmetic Surgery is provided by NHS Choices. Weblink:  
<http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx> and  
<http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx>

## Diagnostic Procedures

Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

Where a General Practitioner/Optometrlist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrlist/Dentist, in order for them to make a decision on future treatment.

## Clinical Trials

The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

## Clinical Exceptionality

If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy.