NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin077
Labiaplasty, vaginoplasty and hymenorrhaphy

Category 1 Interventions – Not routinely commissioned
- Hymenorrhaphy or hymenoplasty

Category 2 Intervention - Only routinely commissioned when specific criteria are met
- Labiaplasty
- Vaginoplasty

Contents

Last Reviewed: March 2024
This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 These policies must be considered in context of a recommendation from the Royal College of Obstetricians and Gynaecologists (RCOG) which states that clinicians have a duty of care to provide accurate information on the diversity of morphology and appearance of the female genitalia. In addition, clinicians who perform these procedures must be aware they are operating without a clear evidence base. More specifically, in August 2021, RCOG called for virginity testing and hymenoplasty to be banned in the UK because there is no medical reason why these should be carried out.

1.1.1 **Hymenorrhaphy** or hymenoplasty surgical repair of the hymen is not routinely commissioned.

1.1.2 **Labiaplasty** is not routinely commissioned unless the patient is aged at least 18 years or older and birth trauma is present

1.1.3 **Vaginoplasty** is not routinely commissioned unless the patient is aged at least 18 years or older and one of the following conditions is present:

- congenital or significant developmental abnormality

OR

- birth trauma

2. Exclusions

2.1 Surgery for cancer, suspected malignancy or repair of cancer-related scarring together with repair of female genital mutilation (FGM) or sexual abuse-related trauma are outside the scope of this policy and are excluded.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 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 expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 It is generally agreed that female genital surgery is considered to be cosmetic unless there is a recognisable disease process. This is confirmed by guidance from the Royal College of Obstetricians and Gynaecologists and the British Society for Paediatric and Adolescent Gynaecology.

4.2 More specifically, the Royal College of Obstetricians and Gynaecologists also recognise there are no medical reasons why hymenoplasty (hymenorrhaphy) should be performed at all and are calling for this procedure to be made illegal.

5. Summary of evidence review and references

5.1 "Female cosmetic genital surgery" is an umbrella term which encompasses labiaplasty, hymenoplasty and vaginoplasty.[1] *Labiaplasty* is the surgical reduction of the size of the labia minora (the flaps of skin either side of the vaginal opening) as a treatment for labia hypertrophy which is yet to be clearly defined in the literature [2] and no consensus exists with respect to its varying grades and classification. [3] *Vaginoplasty* is also known as vaginal reconstruction or vaginal rejuvenation which involves reshaping of the vagina to restore vaginal tone and appearance. [4] *Hymenoplasty* or *hymenorrhaphy* is the surgical restoration or reconstruction of the hymen. [5]

5.2 It has been suggested that women request surgery for reasons of cosmesis to increase self-esteem and improve sexual function.[1] However, it has also been reported that most women cite physical concerns about their genitals as the primary reason for seeking surgery. Some had reported physical discomfort when engaging in physical activity, such as horseback riding, or when wearing tight clothing. Others reported psychological discomfort related to the appearance of their genitals in certain types of clothing such as bathing suits. Intuitively, therefore, one might think that women are most concerned about their labia when undressed when in fact it appears their concerns are both physical and psychological in nature which intrude upon normal, daily activity.[6] In a very recent study (2021), 85% of women undergoing labiaplasty for hypertrophy at a tertiary care centre gave "pain" as their primary motivation. The authors concluded, therefore, that women were mainly motivated by functional concerns.[7]

5.3 It is not surprising that genital plastic surgery for women has come under significant scrutiny both in the media and online. In the absence of measurable standards of care, lack of evidence-based outcome norms and little standardisation either in nomenclature or training requirements, concerns from within the medical profession have been raised.[1] A review of labial surgery in 2010 could find no prospective RCTs and the authors concluded that medically non-essential surgery was being promoted where no data on clinical effectiveness existed.[8] A subsequent qualitative study of post-operative experiences of labiaplasty revealed that online media representations of labial appearance contributed to women's concerns yet most women reported significant improvements in their sexual well-being after surgery. [9]

5.4 Defining “normal” is yet to be established and despite this, one study (2011) measured the physical dimensions of women requesting labia reduction at a London clinic and found their measurements were within normal published limits at that time. [10] Another 2021 study determined what is known in the published literature about normal labial dimensions. This showed significant variation in labial length (range 5 – 100 mm) and width (range 1 – 60 mm). The authors suggested these results could be used in medical textbooks and teaching to ensure medical graduates are sufficiently informed about normal variation in female genital anatomy.[11]

5.5 Regarding the surgical procedure itself, there are few validated, long-term safety or outcome data.[1] Of the few data which are available, it seems that complications with labiaplasty are relatively rare. A retrospective chart review in 113 patients with primary aesthetic labia minora reduction surgery from 2007 – 2014 reported transient symptoms (swelling, bruising or pain) in 15 cases (13.3%), one case (0.8%) of bleeding and 4 cases (3.5%) of patients who required surgical revision.[12] In another smaller study (62 patients), no major complications were reported and 93.5% of patients were symptom-free after labiaplasty although 2/62 (3.2%) required revision.[13]

5.6 Guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) reviewed the ethical considerations related to female genital cosmetic surgery. [4] The College recognises that clinicians have a duty of care to provide accurate information on the diversity of morphology and appearance and to suggest simple measures to relieve any discomfort when no pathology can be identified. Clinicians who perform this procedure must be aware they are operating without a clear evidence base. This procedure shouldn’t be offered to girls <18 years and the College goes on to say that surgery should not be undertaken within the NHS unless it is medically indicated.

5.7 NHS England’s Armed Forces Commissioning Policy Task and Finish Group have also considered genital surgery specifically labiaplasty, vaginoplasty and hymenorrhaphy and all 3 are restricted.[5] Labiaplasty will only be commissioned with recurrent disease or infection or secondary to trauma. Vaginoplasty will only be commissioned for congenital or developmental abnormalities or secondary to trauma. Hymenorrhaphy (hymen reconstruction surgery) is considered to be a cosmetic procedure and will not routinely be funded.

5.8 The British Society for Paediatric and Adolescent Gynaecology (BritSPAG) recognises labiaplasty as a form of female genital cosmetic surgery in the majority of cases. [14] There is no recognisable disease process warranting surgical treatment and no creditable evidence to demonstrate lasting effectiveness along physical, psychological or sexual parameters. Further, there is no scientific evidence to support the practice of labiaplasty and for girls under the age of 18 years, the risk of harm is even more significant. The American College of Obstetricians and Gynaecologists have released similarly restrictive guidance.[15] The emphasis of the American College’s guidance is to focus on education regarding normal vulvar anatomical variations and pubertal changes, assessment of mental and emotional maturity to understand potential risks and complications of labiaplasty, screening for body dysmorphic disorder and a discussion of the non-surgical options (e.g. tucking and lubrication to avoid chaffing).

5.9 It is generally agreed that female genital surgery is a cosmetic procedure although some women may experience functional problems. On that basis, defining “normal” is yet to be established although in practice, there is wide variation in the physical dimensions of the external genitalia. Evidence to define any recognisable disease process or to support surgical repair is distinctly lacking. It is not unreasonable, therefore, to conclude that surgical repair of the labia or vagina for cosmetic reasons only is unacceptable and the only indication for surgery would be where there is a recognised disease or congenital defect.

Hymenoplasty is a special case because it is also generally accepted there are no cases where this should be performed for medical reasons. As a result, RCOG have recently called for a total ban both on virginity testing and hymenoplasty and have urged the government to make these procedures illegal.[16]

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6. Advice and Guidance

6.1 **Aim and Objectives**

- 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.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- 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 in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- 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.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms 'men' and 'women' are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 Core Principles

- 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.

6.3 Individual Funding Requests (Clinical Exceptionality Funding)

- 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 available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 **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

6.5 **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/Optometrist/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/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 **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.

7. Monitoring and Review

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.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 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

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

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

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**
Any in primary position
P05.5 Excision of excess labial tissue
P05.6 Reduction labia minor
P05.7 Reduction labia major
P21.3 Vaginoplasty NEC
P21.4 Vaginoplasty in presence of uterus for absent vagina
P21.5 Vaginoplasty using olive
P21.8 Other specified plastic operations on vagina
P21.9 Unspecified plastic operations on vagina
P15.3 Repair of hymen

9.2 **International classification of diseases (ICD-10)**
a) With or without in any position
N90.6 Hypertrophy of vulva
Z41.1 Other plastic surgery for unacceptable cosmetic appearance

b) With or without in any position
O94 Sequelae of complication of pregnancy, childbirth and the puerperium

c) With or without in any position
Z91.7 Personal history of female genital mutilation

Document Control

Ref:	CMICB_Clin077 – Labiaplasty, vaginoplasty and hymenorrhaphy
Version:	1
Supersedes:	Previous Clinical Commissioning Group (CCG) Policies
Author (inc Job Title):	Consultant in Public Health, NHS Midlands and Lancashire
Ratified by: **(Name of responsible Committee)**	ICB Board
Cross reference to other Policies/Guidance	N/A
Date Ratified:	March 2024
Date Published and where (Intranet or Website):	March 2024 - (Website)
Review date:	March 2029
Target audience:	All Cheshire & Merseyside ICB staff and provider organisations

Version History
Version 1 – March 2024 – Policy ratified by NHS Cheshire & Merseyside ICB