



FEMALE GENITALIA EVIDENCE BASED INTERVENTIONS (EBI) POLICY

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Application Form	Generic EBI Application

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VERSION CONTROL

Document Status:	Current policy
Version:	2324.v5d

DOCUMENT CHANGE HISTORY		
Version	Date	Comments
V8e	December 2015	Remove from the Guidance for Clinicians Document to individual policy
1516.v3	December 2015	Include more data to General Principles item 12 and the background information
1516.v4	July 2017	Change CSU template to SCCG template
1516.v4a	June 2018	3-year review no change to criteria, move to SCCG policy template
1819.v4b	March 2021	3-year policy review – no clinical amendments to criteria, but a change to the wording under 2.5: remove "consideration" and replace with "clinical circumstances prior to a review"
2021.v5a	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.v5b	March 2023	Wording change 3.6
2223.v5d	January 2024	3-year review, no clinical amendments. Amendment to website link on 3.6

Equality Impact Assessment EIA	February 2019
Quality Impact Assessment QIA	March 2018
Sponsoring Director:	Bernie Marden
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1 GENERAL PRINCIPLES (EBI)

- 1.1 Funding approval must be secured prior to a referral for an assessment and/or surgery. Referring patients to secondary care without funding approval having been secured 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
- 1.2 On limited occasions, we may approve funding for an assessment 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 meet the criteria to access treatment in this policy
- 1.3 Funding approval will only be given where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where it is demonstrated that patients have previously been provided with the treatment with limited or diminishing benefit, funding approval is unlikely to be agreed
- 1.4 Receiving funding approval does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment
- 1.5 The policy does not apply to patients with suspected malignancy who should continue to be referred under 2 week wait pathway rules for assessment and testing as appropriate
- 1.6 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)
- 1.7 Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing

2 POLICY CRITERIA

- 2.1 This policy does not apply to genital reconstruction for gender dysphoria which is commissioned by NHS England
- 2.2 Immediate vaginal repair following delivery or revisions post childbirth where there is evidence of pain or discomfort is routinely commissioned (as part of obstetric care and therefore not within the remit of this policy)
- 2.3 Applications **will not** be considered:

- Where patients are below 18 years of age (clinicians must share information with the appropriate authorities)
- 2.4 The following procedures are not routinely commissioned
 - Episiotomy scar revision (generally a cosmetic procedure)
 - Hymenorrhaphy, or hymen reconstruction surgery (a cosmetic procedure)
 - Non-reconstructive vaginoplasty or "vaginal rejuvenation" used to restore vaginal tone and appearance
- 2.5 For any of the clinical circumstances detailed below clinical evidence is required to support the criteria is fulfilled prior to a review of a funding application;

Please refer to item 3 on how to apply for funding on the grounds of clinical exceptionality

- 2.5.1 Labiaplasty for the following indications:
 - Where the labia are unresponsive to repeated treatment for disease or infection or
 - Where repair of the labia is required after significant trauma (Common consequence of childbirth will not be sufficient reason)
- 2.5.2 Vaginoplasty for the following indications:
 - Congenital absence/significant developmental/endocrine abnormalities of the vaginal canal **or**
 - Where repair of the vaginal canal is required after trauma (trauma is a common consequence of childbirth and this will not be a reason for surgery)

3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

- 3.1 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
- 3.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required
- 3.3 Applications cannot be considered from patients personally

- 3.4 Only electronically completed EBI applications will be accepted to the EBI Service
- 3.5 It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the EBI service. This will reassure the service that the patient has a reasonable expectation of the outcome of the application and its context
- 3.6 EBI funding application are considered against clinical exceptionality. To eliminate discrimination for patients, **social**, **environmental**, **workplace**, **and non-clinical personal factors cannot be taken into consideration**

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB EBI webpage <u>Evidence Based Interventions - NHS Somerset ICB</u> and click on the section titled Generic EBI Pathway

- 3.7 Where appropriate photographic supporting evidence can be forwarded with the application form
- 3.8 An application put forward for consideration must demonstrated some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:
 - Significantly different to the general population of patients with the condition in question
 - Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

4 ACCESS TO POLICY

- 4.1 If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067
- 4.2 **Or write to us**: NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

5 REFERENCES

The following sources have been considered when drafting this policy:

- 5.1 NHS Choices
 - http://www.nhs.uk/conditions/pregnancy-and-baby/pages/episiotomy.aspx
- 5.2 Serious Crime Act 2015

http://www.legislation.gov.uk/ukpga/2015/9/part/5/crossheading/female-genital-mutilation/enacted

5.2 Cosmetic procedures - Labiaplasty (vulval surgery) - NHS (www.nhs.uk)