

FUNCTIONAL ELECTRICAL STIMULATION (FES) CRITERIA BASED ACCESS (CBA) POLICY

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Application Form	EBI Generic application form if appropriate to apply

**FUNCTIONAL ELECTRICAL STIMULATION
CRITERIA BASED ACCESS (CBA) POLICY**

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VERSION CONTROL

Document Status:	Current policy
Version:	2223.v3b

DOCUMENT CHANGE HISTORY

Version	Date	Comments
V8e	2015	Remove from Guidance for Clinicians Document to separate Policy
1516.v2a	July 2017	Change CSU template to SCCG template
1516.v2b	June 2021	3 year review, removal of 'Under 18 years of age' under 2.4 Exclusion Criteria
2122.v3	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS email address
2223.v3a	March 2023	Wording change 3.6

Equality Impact Assessment (EIA) Form OR EIA Screening Form completed. Date:	N/A
Quality Impact Assessment (QIA)	1516.v1
Sponsoring Director:	Dr A Murray
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1 GENERAL PRINCIPLES (CBA)

- 1.1 Treatment should only be given in line with these general principles. Where patients are unable to meet these principles, in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB's Evidence Based Interventions Service (EBI) by submission of an EBI application form
- 1.2 Clinicians should assess their patients against the criteria within this policy prior to a referral and/or treatment
- 1.3 Treatment should only be undertaken where the criteria have been met and there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment
- 1.4 Referring patients to secondary / community care without them meeting the criteria or funding approval not 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
- 1.5 On limited occasions, the ICB 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 meets the criteria to access treatment in this policy
- 1.6 Patients should be advised being referred 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
- 1.7 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
- 1.8 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)
- 1.9 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 BASED ACCESS (CBA)

2.1 FES for Upper Limb is not commissioned by the ICB

2.2 Implanted FES is not commissioned by the ICB

2.3 Referrals outside of local pathway: EBI funding authorisation is required by completion of the Generic EBI application form

2.4 Lower Limb FES, external devices are commissioned

Exclusion criteria

- Poor skin condition is a contraindication as sores or irritation prevents the use of self-adhesive electrodes
- Poorly controlled epilepsy: Where epilepsy is controlled by drugs or if there has been no fits experienced for a reasonable period, FES can be used
- A history of significant autonomic dysreflexia in Complete spinal cord injury above T6

2.5 The effect of FES on the unborn child is not known in pregnancy

2.6 Active medical implants such as cardiac pacemakers or other devices must be treated with caution and information must be sought from the device supplier for use of electrical stimulation in their presence

2.7 Additional clinical test may be required to determine the safety of FES

2.8 Patients with a cancerous tumour in the area of the electrical stimulation should be excluded as increased local blood flow may increase tumour growth

2.9 Patients with exposed orthopaedic metal work in the area of electrical stimulation should be avoided

2.10 Outpatient referrals local provision

Patients identified as being suitable for FES will be assessed by an accredited assessor in FES. Patients should be referred by their GP or Medical Consultant to the appropriate therapy service (IRT, Stroke Therapy Team, Neuro Outpatient Therapy at YDH or MPH) specifying FES may be appropriate to ensure the patient is seen by an accredited assessor in FES

2.11 Inpatient referrals local provision

Patients identified as being suitable for FES will be assessed by an accredited assessor in FES

2.12 Community referral local provision

ESD/ ILT therapist referrals/ stroke co-ordinators

2.13 **REFERRAL CRITERIA**

2.13.1 **Neurological deficit due to an upper motor neurone lesion**

An upper motor neurone lesion is defined as one that occurs in the brain or spinal cord at or above the level of T12. Upper motor neurone lesions that may benefit from FES are stroke, multiple sclerosis, incomplete spinal cord injury at T12 or above, cerebral palsy, familial / hereditary spastic paraparesis, head injury and Parkinson's disease

2.13.2 **Dropped foot defined as a deficit of dorsiflexion and / or eversion of the ankle**

- a. While this will be frequently associated with lack of heel strike, FES can be successfully used to correct inversion at first contact to significantly improve the stability of the ankle in the stance phase, improving the safety of gait
- b. A dropped foot can be unilateral or bilateral. In addition to drop foot, deficits in knee flexion or extension, hip extension and abduction and push off at terminal stance can be addressed

2.13.3 **Lower limb: Functional ability**

- a. Able to passively achieve a neutral angle of the ankle
- b. A resistance due to spasticity of the calf muscles can be overcome but fixed contracture preventing plantar grade is a contraindication
- c. Able to obtain standing from sitting unaided
- d. Use of aids such as sticks, frame or crutches is acceptable
- e. Usually able to walk a minimum distance of about 10m
- f. Use of aids such as ankle foot orthosis (AFO), sticks, frame or crutches is acceptable. A reasonable exercise tolerance is required for treatment sessions. However, FES often reduces the effort of walking therefore poor exercise tolerance is only an exclusion criteria in extreme cases
- g. There is no maximum walking distance limit. FES devices have been successfully used in cases where a dropped foot only becomes a significant problem when the device user is tired or when the deficit is relatively mild

2.13.4 **Motivation, understanding and independence**

- a. Able to understand the aims of the treatment and be motivated to comply with treatment protocols

- b. Where appropriate, carer support can assist in using the equipment
Where patients live alone and do not have carer assistance, they must be able to place electrodes and operate the equipment independently
- c. If family or carer support is present, less independence is required

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 applications are reviewed and considered for clinical exceptionality

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB website and input into the 'Search this website' box clinical exceptionality.

Social, Emotional and Environmental factors *i.e. income, housing, environmental pollution, access to services, family, friends, ethnicity, life experiences etc.* CANNOT be considered with an application

- 3.7 Where appropriate photographic supporting evidence can be forwarded with the application form
- 3.8 An application put forward for consideration must demonstrate 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:

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5.1 NICE guidelines IPG278 Jan 2009:
<http://www.nice.org.uk/Guidance/IPG278>