

CLINICAL POLICY ADVISORY GROUP (CPAG)

Functional Electrical Stimulation (FES) for Foot Drop of Neurological Origin Policy

This procedure requires prior approval. The prior approval form can be found under Appendix 3.

Statement

Derby and Derbyshire CCG (DDCCG) has deemed that the wired version of Functional Electrical Stimulation (FES) using skin surface electrodes in adults and children with foot drop of neurological origin should not routinely be commissioned, unless all of the following criteria is met:

- The patient has foot drop caused by upper level nerve damage
- The patient has been assessed by a specialist in foot drop of neurological origin and all treatment options have been considered
- There is evidence that foot drop has caused trips or falls, or gait issues causing significant clinical problems
- The patient can walk a minimum of 10 meters independently (+/- aids)
- The patient can physically manage a FES (+/- minimal assistance)
- The patient's cognitive ability is such that they can manage a FES independently
- The patient does not have co-morbidities which would affect their capacity to benefit from FES
- The patient does not have any of the accepted clinical contraindications to FES

Exclusion Criteria

Other types of FES (implanted or wireless) are not commissioned as this policy only covers lower limb FES for foot drop.

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the CCG.

1. Background

Upper motor neurone lesions caused by multiple sclerosis, stroke, cerebral palsy or spinal cord injury have a range of physical consequences, with foot drop being one of the most common manifestations.

Foot drop results from weakness or lack of voluntary control within the ankle and foot dorsiflexors. This causes the toes to drag, and the foot to drop during the normal gait pattern, which is likely to increase the risk of falls. Other approaches to treating foot drop include physiotherapy and ankle-foot orthoses (AFO).

FES has been designed to help people with neurological lesions, including drop foot, to move more easily. Skin surface electrodes are placed over the nerve and connected by leads to a stimulator unit, controlled by a foot switch. It works by producing muscle contractions that mimic normal voluntary gait movement by applying electrical pulses to nerves across the skin.

2. Recommendation

Derby and Derbyshire CCG (DDCCG) does not routinely commission the wired version of Functional Electrical Stimulation (FES) using skin surface electrodes in adults and children with foot drop of neurological origin, unless all of the following criteria are met:

- The patient has foot drop caused by upper level nerve damage
- The patient has been assessed by a specialist in foot drop of neurological origin and all treatment options have been considered
- There is evidence that foot drop has caused trips or falls, or gait issues causing significant clinical problems
- The patient can walk a minimum of 10 meters independently (+/- aids)
- The patient can physically manage a FES (+/- minimal assistance)
- The patient's cognitive ability is such that they can manage a FES independently
- The patient does not have co-morbidities which would affect their capacity to benefit from FES
- The patient does not have any of the accepted clinical contraindications to FES

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Exceptional Circumstances

DDCCG will consider individual cases for funding outside this commissioning policy in

accordance with their Individual Funding Request (IFR) Policy which sets out a decision making framework for determining these cases. For an IFR request to be considered, it must be demonstrated that the patient fulfils the strict criteria for exceptionality.

It should be noted that the criteria for exceptionality is very unlikely to be satisfied if an individual is part of an identifiable cohort of patients, who at the same disease stage would derive similar benefit from the intervention.

3. Rationale for Recommendation

The evidence for efficacy and safety of FES have been reviewed by NICE in IPG278 (2009) which states that the efficacy (improving gait) and safety of Functional Electrical Stimulation (FES) for foot drop of central neurological origin appears adequate to support its use under normal clinical governance and audit arrangements.

The SIGN Management of patients with stroke: Rehabilitation, prevention and management of complications, and discharge planning national clinical guideline (June 2010) suggests that FES for drop-foot can be considered for stroke rehabilitation to help improve gait, balance and mobility.

4. Useful Resources

- National Institute for Health and Care Excellence. Treating drop foot using electrical stimulation, Information for people who use NHS services, Information about NICE interventional procedure guidance 278, January 2009, <https://www.nice.org.uk/guidance/ipg278/resources/treating-drop-foot-using-electrical-stimulation-pdf-310962205>

5. References

- East Midlands Affiliated Commissioning Committee. Commissioning Policy for Functional Electrical Stimulation for Foot Drop of Neurological Origin, version 1, November 2017.
- National Institute for Health and Care Excellence, 2009. Interventional Procedure Guidance: Functional electrical stimulation for drop foot of central neurological origin, accessed 04/11/20, <http://www.nice.org.uk/IPG278>
- Scottish Intercollegiate Guidelines Network. Management of patients with stroke: Rehabilitation, prevention and management of complications, and discharge planning A national clinical guideline. SIGN 118 June 2010. <https://www.sign.ac.uk/media/1056/sign118.pdf>

6. Appendices

Appendix 1- Consultation

All relevant providers/stakeholders will be consulted via a named link consultant/specialist. Views expressed should be representative of the provider/stakeholder organisation. CPAG will consider all views to inform a consensus decision, noting that sometimes individual views and opinions will differ.

Consultee	Date
In development: <ul style="list-style-type: none"> • Nottingham City Council Public Health Department (Public Health Consultant, Nottinghamshire County Council Public Health Department) • NHS Nottingham City CCG • Mobility and Specialised Rehabilitation Centre, Sheffield Teaching Hospitals • Derby Gait and Fes Service, Derby Teaching Hospitals • West Midlands Rehabilitation Centre, Birmingham Community Healthcare 	November 2016 to March 2017
East Midlands Affiliated Commissioning Committee's Clinical Priorities Steering Group (EMACC's CPSG)	10/03/17 & 28/03/17
CCG Individual Funding Request Managers	28/03/17
Approved By EMACC with minor amendments	7/04/17
Which group	See consultation P2
Public Health Input	See consultation P2
Derbyshire Commissioning Policy Affiliated Committee	15/11/18
Planned Care Manager (inc. East Midlands Affiliated Commissioning Committee), Nottingham and Nottinghamshire CCG)	October 2020
Individual Funding Request Manager/Service Restricted Manager (Nottingham and Nottinghamshire CCG)	October 2020
Team leader / Specialist Physiotherapist, Derby Gait and FES Services (UHDBFT)	October 2020
Cost per case co-ordinator, Strategy and Operations (Sheffield Teaching Hospitals NHSFT)	October 2020
Clinical Policy Advisory Group	November 2020
East Midlands Affiliated Commissioning Committee	December 2020
CLCC	December 2020

Appendix 2- Document Update

Document Update	Date Updated
East Midlands Affiliated Commissioning Committee Commissioning (EMACC) Policy – version 1	November 2017
Derby and Derbyshire CCG Policy (based on EMACC's policy) – version 1	November 2018
Version 2 – policy reworded and reformatted to reflect and align to the new organisation's clinical policy format. Removal of the criteria 'Clear FES treatment goals and expectations of benefit are outlined' and criteria for funding of maintenance and support for patients who are already being treated with FES. Updated prior approval form has been added to the policy under Appendix 3.	November 2020

Appendix 3- Prior Approval Form for Secondary Care

Send completed prior approval form to: ddccg.ifrfundingrequest@nhs.net



Derby and Derbyshire
Clinical Commissioning Group

Prior Approval to be used in conjunction with:
A commissioning policy: Orthotic Functional Electrical Stimulation (FES) for foot drop of neurological origin.

1. Patient and request details.	
Date of Request	
Patients NHS Number, initials and date of birth	
Responsible primary care organisation (CCG)	
Relevant diagnosis / indication	
Specialist who has made referral (name, job title, organisation)	
Proposed service provider	
Prior approval form completed by (name, job title, organisation)	
<i>Please note: completion should be by a clinician who knows and has assessed this patient, or be based on documentary evidence such as assessments, sufficient to complete the form.</i>	

2. Pre-screening prior to Assessment for FES		
Patient meets policy criteria outlined in the DDCCG Commissioning Policy for the use of FES including the following (please check relevant boxes and provide detail where indicated):		
	YES	NO
Has the patient been assessed by a specialist in foot drop of neurological origin?	<input type="checkbox"/>	<input type="checkbox"/>
Have a range of treatment options been considered?	<input type="checkbox"/>	<input type="checkbox"/>
A referral letter must be submitted with this form. Referral or clinic letter attached?	<input type="checkbox"/>	<input type="checkbox"/>
What alternatives have been considered and / or tried?		
Please provide details (including outcomes):		
Can the patient walk more than or equal to 10 meters independently (+/- walking aids)?	<input type="checkbox"/>	<input type="checkbox"/>
Has the patient reported any trips or falls or do they have gait problems related to foot drop?	<input type="checkbox"/>	<input type="checkbox"/>
Can the patient physically manage a FES (+/- minimal assistance)?	<input type="checkbox"/>	<input type="checkbox"/>
Is the patient's cognitive ability such that they can manage a FES independently?	<input type="checkbox"/>	<input type="checkbox"/>
Does the patient have any co morbidities which may affect their capacity to benefit from FES?	<input type="checkbox"/>	<input type="checkbox"/>
Please provide details:		
Does the patient have any of the following co-morbidities:	YES	NO
Fixed contractures of the joint associated with muscles to be stimulated?	<input type="checkbox"/>	<input type="checkbox"/>
Broken or poor condition skin?	<input type="checkbox"/>	<input type="checkbox"/>
Inability to stimulate site?	<input type="checkbox"/>	<input type="checkbox"/>

Acute concurrent DVT?	<input type="checkbox"/>	<input type="checkbox"/>
Receptive dysphasia?	<input type="checkbox"/>	<input type="checkbox"/>
Complete peripheral nerve damage?	<input type="checkbox"/>	<input type="checkbox"/>
Pacemaker in situ?	<input type="checkbox"/>	<input type="checkbox"/>
Life expectancy < 12 months?	<input type="checkbox"/>	<input type="checkbox"/>
Any other accepted contraindications to FES e.g. pregnancy, uncontrolled epilepsy etc?	<input type="checkbox"/>	<input type="checkbox"/>
If yes to any of the above, please provide details:		

<p>Approval for FES will be granted on condition that:</p> <ul style="list-style-type: none"> The patient meets the criteria outlined in the policy The patient has agreed to proceed with the treatment The clinical team provides the clinical information requested below as required. Approved for FES Yes <input type="checkbox"/> / No <input type="checkbox"/> Date: _____ <p>Approved on behalf of NHS Derby and Derbyshire CCG by: _____</p>
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3. Pre FES	
Patient's baseline clinical condition, including: <ul style="list-style-type: none"> Predominant symptoms and measures of effort, walking speed, gait, trips and falls etc. SF36 or EQ-5D assessment Co morbidities 	

4. Follow up post procedure	
Date of reassessment:	Clinic letter attached (please check box if yes) <input type="checkbox"/>
Patient has derived documented clinical benefit from FES	<input type="checkbox"/>
Patient wishes to continue with FES (please check box if yes)	<input type="checkbox"/>
Patient has experienced complications due to FES (please check box if yes)	<input type="checkbox"/>
If ticked yes, please give details:	
Patient's clinical condition one year after treatment: <ul style="list-style-type: none"> Predominant symptoms and measures of effort, walking speed, gait, trips and falls etc. SF36 or EQ-5D assessment Co-morbidities 	