

Policy for Functional Electrical Stimulation (FES)

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Name of responsible Committee and date approved or recommended to Integrated Care Board:	Finance and Performance Committee
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Expiry Date:	December 2027
Name of author and title:	Public Health Warwickshire & ICB Medical Directorate
Name of reviewer and title:	Dr Mike Caley, Deputy Chief Medical Director
Department:	Medical Directorate

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.
August 2024	V2	<ul style="list-style-type: none"> • Formatting changes. • Change of policy category for FES from not normally routinely commissioned to prior approval. 	Clinical Commissioning Policy Development Group – 20 February 2024 and 20 August 2024

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1. Category: Prior Approval

Prior approval from the Integrated Care Board (ICB) will be required before any treatment proceeds in secondary care unless an alternative contract arrangement has been agreed with the ICB that does not necessitate the requirement of prior approval before treatment.

2. Background

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity relating to the approach to Functional Electrical Stimulation (FES) by the Integrated Care Board (ICB).

Conditions affecting upper motor neuronal pathways are conditions of central neurological origin (CNO) and include stroke, cerebral palsy or multiple sclerosis. Footdrop can occur as a result of a condition of CNO. It is the inability to dorsiflex the foot (lift the toes) which can result in an abnormal, slow, tiring and sometimes unsafe gait.

Treatments for drop foot include physiotherapy, orthotic devices, medical therapy and electrical stimulation of the affected nerves and surgery.

First-line treatment is usually physiotherapy and/or the use of an ankle foot orthosis (AFO). An AFO is a device, usually made of plastic, which is worn on the lower part of the leg and on the foot. It is used to align the lower leg correctly and control the motion of the ankle and foot, to provide stability and improve gait. Evidence will be required to demonstrate that first-line treatments have been tried.

3. Eligibility Criteria

In accordance with national guidelines carefully selected patients may be eligible to be considered for FES if certain pre-requisite criteria are fulfilled:

- The individual has a upper motor neuron lesion resulting from stroke, multiple sclerosis, cerebral palsy or spinal cord injury (but has an intact peroneal nerve);
- There is evidence that the dropped foot interferes significantly with the individual's day to day living, arising from problems such as frequent falls and severe fatigue;
- There is evidence that FES has been recommended for the individual after a thorough assessment of their suitability by the local physiotherapy service or MDT specialising in rehabilitation (this recommendation must specify how any benefit will be measured for the individual);
- There is evidence to demonstrate that first-line treatments have been tried.

Note: If a patient meets the policy criteria it is expected that the patient will demonstrate a positive trial of FES before proceeding to a permanent stimulator. In this case the patient will proceed with a surface electrode device, but an additional individual funding request will need to be made if an implanted electrode is being considered.

4. Commissioning position

For all other indications the use of FES and FES cycle are interventions **NOT ROUTINELY COMMISSIONED** due to a lack of high quality evidence of clinical and cost effectiveness.

For patients who DO NOT meet the eligibility criteria, the ICB will only consider funding the treatment if an Individual Funding Request (IFR) detailing the patient's clinical presentation is submitted to the ICB.

5. Guidance

NICE Interventional procedures guidance (IPG278) Functional electrical stimulation for drop foot of central neurological origin. Published date: January 2009 <https://www.nice.org.uk/guidance/ipg278>

Miller Renfrew, L. et al. (2019b) 'Evaluating the effect of functional electrical stimulation used for foot drop on aspects of health-related quality of life in people with multiple sclerosis', International Journal of MS Care, 21(4), pp. 173–182. doi:10.7224/1537-2073.2018-015.

Miller, L. et al. (2017) 'Functional electrical stimulation for foot drop in multiple sclerosis: A systematic review and meta-analysis of the effect on gait speed', Archives of Physical Medicine and Rehabilitation, 98(7), pp. 1435–1452. doi:10.1016/j.apmr.2016.12.007.

Buentjen, L., Kupsch, A., Galazky, I. et al. Long-term outcomes of semi-implantable functional electrical stimulation for central drop foot. J NeuroEngineering Rehabil 16, 72 (2019). [Long-term outcomes of semi-implantable functional electrical stimulation for central drop foot | Journal of NeuroEngineering and Rehabilitation | Full Text \(biomedcentral.com\)](#)

Robison, J. et al. (2022) Augmenting gait in a population exhibiting foot drop with adaptive functional electrical stimulation [Preprint]. doi:10.1101/2022.04.27.22273623.

Gervasoni E, Parelli R, Uszynski M, Crippa A, Marzegan A, Montesano A, Cattaneo D. Effects of Functional Electrical Stimulation on Reducing Falls and Improving Gait Parameters in Multiple Sclerosis and Stroke. PM R. 2017 Apr;9(4):339-347.e1.

Hausmann J, Sweeney-Reed CM, Sobieray U, et al. Functional electrical stimulation through direct 4-channel nerve stimulation to improve gait in multiple sclerosis: a feasibility study. J Neuroeng Rehabil. 2015;12:100

Malešević, J. et al. (2021) 'Smart protocols for physical therapy of foot drop based on functional electrical stimulation: A case study', Healthcare, 9(5), p. 502. doi:10.3390/healthcare9050502.

6. Equality and Quality Impact Assessment Tool

The following assessment screening tool will require judgement against all listed areas of risk in relation to quality. Each proposal will need to be assessed whether it will impact adversely on patients / staff / organisations.

Insert your assessment as positive (P), negative (N) or neutral (N/A) for each area.

Record your reasons for arriving at that conclusion in the comments column. If the assessment is negative, you must also calculate the score for the impact and likelihood and multiply the two to provide the overall risk score. Insert the total in the appropriate box.

Quality Impact Assessment

Quality and Equality Impact Assessment

Scheme Title:	Policy for Functional Electrical Stimulation		
Project Lead:	Lucy Dyde, IFR Team Manager	Senior Responsible Officer:	Dr Michael Caley, Deputy CMO
		Quality Sign Off:	Quality team as below
Intended impact of scheme:	<p>To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility.</p> <p>The policy for Functional Electrical Stimulation supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness and desired outcomes for patients it is intended for.</p>		
How will it be achieved:	Through the process detailed in this document.		

Name of person completing assessment:	Lucy Dyde
Position:	IFR Team Manager
Date of Assessment:	06 September 2024

Quality Review by:	Mary Mansfield, Sam Collier, Dawn Baker, Annette Walker, Anna Crane
Position:	Team Members
Date of Review:	19 09 2024

High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		OUTCOME ASSESSMENT (Please tick one)			Evidence/Comments for answers	Risk rating (For negative outcomes)			Mitigating actions
		Positive	Negative	Neutral		Risk impact (I)	Risk likelihood (L)	Risk Score (IxL)	
Duty of Quality Could the scheme impact positively or negatively on any of the following:	Effectiveness – clinical outcome	✓			Policy to implement access for eligible patients to receive clinically effective NHS funded treatment following NICE IPG278 and PubMed national evidenced based guidance.				
	Patient experience	✓			Policy to implement access for eligible patients who will be assured that they are accessing evidenced based practice to receive				

					clinically effective NHS funded treatment.				
	Patient safety	✓			The provider will follow the Patient Safety Incident Response Framework (PSIRF) national guidance on reporting learning from patient safety incidents as per individual policy/procedures to protect patients and maintain safety.				
	Parity of esteem	✓			Policy to implement access for eligible patients to receive clinically appropriate treatment which includes access to mental health and physical health support within the designated service, where applicable following NICE IPG278, PubMed national evidenced based guidance and best practice.				
	Safeguarding children or adults	✓			Usual ICB and/or Provider Safeguarding policies and mechanisms will apply.				
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	✓			Patients eligible for NHS funded treatment will experience improved access to service and desired outcome.				
	Ensuring people have a positive experience of	✓			Increased opportunity for patients to access the				

	care				service locally and nationally via patient choice.				
	Preventing people from dying prematurely			✓	Policy to implement access for eligible patient to receive clinically effective treatment.				
	Helping people recover from episodes of ill health or following injury	✓			Policy to implement access for eligible patients to receive NHS funded treatment for Footdrop resulting from CNO causing the inability to dorsiflex the foot which can result in an abnormal, slow, tiring and sometimes unsafe gait.				
	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓			The ICB expectation is that all providers of service hold an NHS standard contract where delivery of the service is stipulated under the core requirements to safeguard quality of care in line with the Care Quality Commission (CQC) "quality statements".				
Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors	✓			Patients eligible for this NHS funded treatment for Footdrop resulting from CNO causing the inability to dorsiflex the foot which can result in an abnormal, slow, tiring and sometimes unsafe gait.				
	Access to the highest			✓	Policy to implement				

	quality urgent and emergency care				access for eligible patients to receive clinically effective treatment following NICE IPG278, PubMed national evidenced based guidance and best practice.				
	Convenient access for everyone	✓			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive NHS funded treatment.				
	Ensuring that citizens are fully included in all aspects of service design and change	✓			Nationally patient engagement and participation has been key to the policy design Patients are invited to participate in current providers National/Local staff satisfaction surveys to ensure ongoing engagement continues.				
	Patient Choice	✓			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive clinically effective NHS funded treatment.				
	Patients are fully empowered in their own	✓			Eligible patients will be fully involved in their care				

	care				planning through shared decision-making, personalised care, and support planning following NICE IPG278, PubMed national evidenced based guidance and best practice.				
	Wider primary care, provided at scale			✓	Policy to implement access for eligible patients to receive clinically effective NHS funded treatment within the Secondary Care services under patient choice.				
Access Could the proposal impact positively or negatively on any of the following:	Patient choice	✓			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive clinically effective NHS funded treatment.				
	Access	✓			This policy applies to all patients registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible patients to receive clinically effective NHS funded treatment within the Secondary Care services under patient choice.				

	Integration	✓			There is collaboration across the pathway at system level across primary and secondary care.				
Compliance with NHS Constitution	Quality of care and environment	✓			The ICB expectation is that all providers of service hold an NHS standard contract where delivery of the service is stipulated under the core requirements to safeguard quality of care in line with the Care Quality Commission (CQC) "quality statements".				
	Nationally approved treatment/drugs	✓			Policy to implement access for eligible patients to receive clinically effective NHS funded treatment following NICE IPG278, PubMed national evidenced based guidance and best practice.				
	Respect, consent and confidentiality	✓			All usual ICB and/or Provider respect, consent and confidentiality policies and mechanisms will apply.				
	Informed choice and involvement	✓			Patients will be fully involved in their care planning through shared decision-making, personalised care, and support planning following				

					PubMed national evidenced based guidance.				
	Complain and redress	✓			Usual ICB and/or Provider compliment, complaint and redress policies and mechanisms will apply				

*Risk score definitions are provided in the next section.

Equality Impact Assessment

Project / Policy Details

What is the aim of the project / policy?

To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility.

The policy Functional Electrical Stimulation supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness and desired outcomes for patients it is intended for.

Who will be affected by this work? e.g staff, patients, service users, partner organisations etc.

Patients

Is a full Equality Analysis Required for this project?

Yes	Proceed to complete this form.	No	Explain why further equality analysis is not required.
			If no, explain below why further equality analysis is not required. For example, the decision concerned may not have been made by the ICB or it is very clear that it will not have any impact on patients or staff.

Equality Analysis Form

1. Evidence used

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

NICE Interventional procedures guidance (IPG278) Functional electrical stimulation for drop foot of central neurological origin. Published date: January 2009

<https://www.nice.org.uk/guidance/ipg278>

Miller Renfrew, L. et al. (2019b) 'Evaluating the effect of functional electrical stimulation used for foot drop on aspects of health-related quality of life in people with multiple sclerosis', International Journal of MS Care, 21(4), pp. 173–182. doi:10.7224/1537-2073.2018-015.

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2. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: A person belonging to a particular age (e.g. 32 year olds) or a range of ages (e.g. 18-30 year olds)

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Disability: A person has a disability if he/she has a physical, hearing, visual or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Gender reassignment (including transgender): Where a person has proposed, started or completed a process to change his or her sex.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Marriage and civil partnership: A person who is married or in a civil partnership.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Pregnancy and maternity: A woman is protected against discrimination on the grounds of pregnancy and maternity. With regard to employment, the woman is protected during the period

of her pregnancy and any statutory maternity leave to which she is entitled. Also, it is unlawful to discriminate against women breastfeeding in a public place.		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
Race: A group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
Religion or belief: A group of people defined by their religious and philosophical beliefs including lack of belief (e.g. atheism). Generally a belief should affect an individual's life choices or the way in which they live.		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
Sex: A man or a woman		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
Sexual orientation: Whether a person feels generally attracted to people of the same gender, people of a different gender, or to more than one gender (whether someone is heterosexual, lesbian, gay or bisexual).		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
Carers: A person who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
Other disadvantaged groups:		
This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.		
3. Human Rights		
FREDA Principles / Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility. The policy for Functional Electrical Stimulation supports the objective to prioritise resources and

		provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.
Respect – right to have private and family life respected	How will the person’s right to respect for private and family life, confidentiality and consent be upheld?	The patient will not be contacted by the ICB. If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	This policy is applied to all patients of the NHS Coventry and Warwickshire Integrated Care Board to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	All communication, written or verbal, will be provided in a confidential, clear, understandable, format.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	Individuals will have the opportunity to discuss their healthcare with the requesting clinician.

		If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.	
Right to Life	Will or could it affect someone's right to life? How?	No	
Right to Liberty	Will or could someone be deprived of their liberty? How?	No	
4. Engagement, Involvement and Consultation			
If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:			
Engagement Activity	Protected Characteristic/ Group/ Community	Date	
N/A	N/A	N/A	
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us So we will):			
N/A			
5. Mitigations and Changes			
Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the recommendations and any changes to the proposal arising from the equality analysis.			
N/A			
6. How will you measure how the proposal impacts health inequalities?			
e.g Patients with a learning disability were accessing cancer screening in substantially lower numbers than other patients. By revising the pathway the ICB is able to show increased take up from this group, this is a positive impact on health inequalities.			
You can also detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract.			
Requests will be managed on a prior approval basis by the IFR team. Activity is monitored through Acute Contracting/Business Intelligence who will monitor the activity and review as appropriate.			
7. Is further work required to complete this assessment?			
Please state what work is required and to what section. e.g additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g disability).			
Work needed	Section	When	Date completed

N/A	N/A	N/A	N/A
8. Sign off			
The Equality Analysis will need to go through a process of quality assurance by a Senior Manager within the department responsible for the service concerned before being submitted to the Policy, Procedure and Strategy Assurance Group for approval. Committee approval of the policy / project can only be sought once approval has been received from the Policy, Procedure and Strategy Assurance Group.			
Requirement	Name	Date	
Senior Manager Signoff	Dr Michael Caley, Deputy CMO	09.09.24	
Which committee will be considering the findings and signing off the EA?	F&P	04.12.2024	
Approved by the Policy Procedure and Strategy Assurance Group.			

Once complete, please send to the ICB's Governance Team.