NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin064
Foot Drop, Functional Electrical Stimulation (FES)

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

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 Functional electrical stimulation (FES) is routinely commissioned for foot drop if both of the following criteria are satisfied:

- Patients have upper motor neurone lesions such as stroke, MS or spinal-cord injury.

AND

- Patient selection has been performed by a multidisciplinary specialist rehabilitation team.

NB. For clinical reasons, patients with any of the following conditions are excluded from treatment:

- Poor skin condition or chronic oedema at the site of stimulation (sores or irritation prevents the use of self-adhesive electrodes).
- Active deep vein thrombosis (DVT).
- Poorly controlled epilepsy (if no convulsions have been experienced for a reasonable period, FES may be appropriate).
- Confirmed or potential pregnancy (the effect of FES on the unborn child is unknown).
- Certain presence of medical implant e.g. cardiac pacemaker.
- Presence of a cancerous tumour in the intended area of electrical stimulation (electrical stimulation may increase local blood flow which could result in increased tumour growth).
- Exposed orthopaedic metalwork in the area of electrical stimulation.

1.2 FES is not routinely commissioned in any other motor neurone lesions and/or in upper limbs.

2. Exclusions

2.1 None.

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 The policy statement has been developed to maintain consistency with recommendations from the National clinical FES centre in Salisbury district hospital and also NICE guidance.

5. Summary of evidence review and references

5.1 This policy is principally driven by NICE Interventional Procedure Guidance IPG 278, "functional electrical stimulation for drop foot of central neurological origin" (2009). This recommends the use of FES for drop foot provided that normal arrangements are in place for clinical governance, consent, and audit. NICE also stipulate that patient selection should involve a multidisciplinary team, specialising in rehabilitation.

5.2 However, it is worth pointing out that the underpinning data which NICE rely on comprise a handful of studies (one meta-analysis, 2 RCTs and a single case series) with very low patient numbers and short follow-up (12 – 26 weeks). The majority of evidence relates to chronic stroke patients. It also has to be emphasised that interventional procedure guidance is generally not considered to be as robust as other types of NICE guidelines.

5.3 A rapid review of the literature identified a recent systematic review and meta-analysis (May 2020) on the impact of FES combined with physiotherapy on post stroke gait speed. This revealed low quality of evidence for a positive effect of FES in this context and because of the high heterogeneity, the authors warned that the results must be interpreted carefully. The 5-year cost of this intervention is around £3000 – £4000 per machine.

5.4 With the exception of Shropshire, the neighbouring CCGs of Mersey, South Staffordshire and Greater Manchester have the same or similar policies in place

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)**

A701 Implantation of neurostimulator into peripheral nerve
A704 Insertion of neurostimulator electrodes into peripheral nerve
A708 Other specified neurostimulation of peripheral nerve

9.2 **International classification of diseases (ICD-10)**

None

Document Control

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