Functional Electrical Stimulation Commissioning Statement

Commissioning Statement: 18

Treatment	Functional Electrical Stimulation Implantable Device
For the treatment of	Functional Electrical Stimulation for "drop foot" of central neurological origin
Background	Functional electrical stimulation (FES) is a treatment that uses the application of small electrical charges to improve mobility. It is particularly used as a treatment for drop foot. Drop foot is caused by disruption in the nerve pathway to and from the brain, rather than in nerves within the leg muscles. This commissioning policy is needed because, although requests for the standard skin-surface PACE FES device for drop foot are routinely commissioned, requests for wireless and implantable devices are only considered in exceptional clinical circumstances via referral to the Individual Funding Request Panel (IFR). **Details of costs** **Standard FES device** – All potential patients need to attend an initial assessment appointment. The following costs cover the load of the stimulation devices, consumables and clinician time. The cost of the initial assessment is £140. The cost of each further follow up appointment is £300. There are usually five appointments in the first year - £1640 in total, and one or two appointments in subsequent years (£ 300 - £ 600). No prior authorisation required **Implantable FES device** (STIMuSTEP) – cost of implant £6,442; ongoing costs £351 per year. The cost of treatment for each patient is subject to inflation rises.
Commissioning position	NHS Vale of York CCG routinely commission Functional Electrical Stimulation for drop foot, with the non-implantable device, in line with NICE IPG278[1], provided normal arrangements are in place for clinical governance, consent and audit. The CCG do **not** routinely commission the wireless or implantable device. Funding will only be considered where there are exceptional clinical circumstances. The clinician needs to submit an application to the CCG's Individual Funding Request Panel (IFR).
Summary of evidence / rationale	Drop foot is inability to lift the foot and toes in the swing phase of the gait when walking. This can cause abnormal gait, reduced walking speed and an increased risk of falls. This condition is present in around 20% of patients surviving a stroke. It is also associated with multiple sclerosis (MS) and other neurological conditions. FES involves the application of electrical pulses to the common peroneal nerve. The pulses are produced by a stimulator unit worn externally and delivered via skin surface (or implanted electrodes). The aim is to produce muscle contractions that mimic normal voluntary movement lifting the foot so that it does not drag on the ground, and so improve gait. A body of evidence, based largely on uncontrolled observational studies in patients with stroke with drop foot and patients with multiple sclerosis with drop foot, using heterogeneous outcome measures, indicates that functional electrical stimulation (FES) (mainly using surface electrodes) is associated with improved walking speed and reduced walking effort[2].

	There are preliminary findings of a therapeutic effect of FES use in patients in the chronic phase of stroke rehabilitation. Three large randomised controlled trials are underway in chronic stroke patients which may provide data on comparison with the ankle foot orthosis[2]. There are few safety concerns around the use of surface-applied FES and patient acceptability appears to be high, however the use of implanted electrodes may be associated with more serious adverse events[2]. A recent UK economic model showed FES in addition to usual physiotherapy care, compared with usual physiotherapy care alone in patients who have suffered a stroke, had a conservative base case cost per QALY of approximately £20,000 (or over £50,000 for the first year and dropping to around £10,000)[3]. No cost effectiveness evidence was identified for other patient groups. Recommendations Functional electrical stimulation can be used for drop foot of central neurological origin, in line with NICE IPG 278, provided normal arrangements are in place for clinical governance, consent and audit. Patient selection for implantable FES for drop foot of central neurological origin should involve a multidisciplinary team specialising in rehabilitation. The IPG also suggests that further publication on the efficacy of FES would be useful, specifically including patient-reported outcomes, such as quality of life and activities of daily living, and these outcomes should be examined in different ethnic and socioeconomic groups
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Author	Dr Alison Forrester, Healthcare public health advisor, CYC and NYCC
Responsible Officer	Shaun O'Connell, GP Lead, valeofyork.contactus@nhs.net

References:

1. NICE IPG 278 Functional Stimulation for drop foot of central neurological origin (March 2009) http://publications.nice.org.uk/functional-electrical-stimulation-for-drop-foot-of-central-neurological-origin-ipg278

2. Evidence note 46 The use of functional electrical stimulation (FES) in adults with dropped foot (This evidence note updates evidence note 25 published in October 2008.) http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg_-_evidence_notes/evidence_note_46.aspx

3. Centre for Evidence-based Purchasing. Economic report: functional electrical stimulation for drop foot of central neurological origin. 2010 [cited 2013 May 24]. Available from: http://nhscep.useconnect.co.uk/ShowDocument.ashx?id=291&i=true