LOW PRIORITY PROCEDURE – Policy
Partially Excluded (PE) Policy - Functional Electrical Stimulation

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Policy start date: August 2013
Review date: August 2015

Policy summary

Functional electrical stimulation (FES) for the treatment of dropped foot in patients with neurological conditions is considered a low priority procedure and will not normally be funded.

Background to the condition and treatment

Dropped foot is defined as the inability to activate the ankle dorsiflexors, and lift the foot from the ground during the swing phase of gait. It is a common manifestation of upper motor neurone lesions and results from lack of voluntary control in the ankle and foot dorsiflexors, causing the toes to drag during the normal gait pattern.

Conventional approaches to treating foot drop include physiotherapy, orthotic devices such as ankle foot orthosis (AFO), electrical stimulation of the affected nerves, and surgery. These options can be used alone or in combination with one another. First-line treatment is usually physiotherapy or the use of an AFO.

Functional electrical stimulation (FES) has been developed as an alternative or adjunct to the above treatments. It uses a stimulator to deliver electrical pulses to the common peroneal nerve (which must be intact), thus activating the ankle dorsiflexors during the swing phase of gait and mimicking normal voluntary gait movement. In the UK, individuals are typically offered the use of a FES device with skin surface electrodes, after which they are assessed to determine if there has been any improvement in their gait.

Rationale behind policy decision

Evidence of clinical effectiveness

Recent systematic reviews that assessed the available literature were equivocal with regards its clinical effectiveness. The methodological quality of the evidence is poor. The small number of randomised controlled studies demonstrated variable results, with some in favour of FES and others demonstrating no difference or negative effects compared with control groups. Studies of the highest methodological quality tend to demonstrate the least benefit for FES.

The comparator for FES is of crucial importance. Much of the evidence relies upon a comparison with physiotherapy alone, whereas treatment guidelines that do recommend FES will often place it as an alternative or subsequent treatment to AFO. In fact, of the small number of studies that compare FES against AFO, the evidence either shows no significant difference in outcomes between the two or is at best equivocal.

Evidence of cost effectiveness
FES is associated with modest overall costs, requiring relatively large up-front hardware costs, some on-going hardware costs, and a significant number of clinic visits especially in the first year. In addition, available cost effectiveness analyses (although yield cost per QALY which meets conventional limits on cost-effectiveness for treatments within the NHS) rely upon a number of modelling parameters which may be considered biased in favour of FES – for instance, an estimate of efficacy of 74% seems generous in light of the results of published randomised controlled trials. Further, no sensitivity analysis was performed with respect to the published economic appraisal. In addition, the cost analysis considers FES compared with physiotherapy alone whereas treatment guidelines recommend FES as an alternative to AFO. It is therefore not clear what the cost-effectiveness is of FES compared with AFO.

Other NHS organisational funding policies

A comparison of the clinical policies of various NHS commissioning organisations with respect to FES shows significant variability across organisations. There is no consistent national policy with respect to FES one way or the other. This therefore suggests the lack of strong evidence for or against FES.

References


