Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	8Th September 2015
Appraisal & Details	**Orthotic functional electrical stimulation (FES) for drop foot of neurological origin.** The Northern NHS Treatment Advisory Group was requested by specialists to conduct a re-appraisal of the use of skin surface functional electrical stimulation (as an option where ankle foot orthotics have failed) for orthotic correction of drop foot of central neurological origin. FES devices are considered Class II Medical Devices by the MHRA.
Recommendation	**The Northern NHS Treatment Advisory Group recommends skin surface functional electrical stimulation for orthotic correction of 'drop foot' as an option for patients who fulfil all of the following criteria:** • **Drop foot is impeding gait and in whom the use of all orthotics (AFO) has proven to be unsuccessful following specialist assessment.** • **The patient has demonstrable functional improvement from an individual trial of FES** • **The intervention is recommended by a multidisciplinary team specialised in rehabilitation.** The group agreed that any use of FES should be assessed and reviewed regularly as part of an approved specialist service under a defined protocol for use such as that proposed by Northumberland, Tyne and Wear Trust.
Clinical evidence summary	The NICE IPG number 287 (2009) states that the current evidence on the safety and efficacy of FES for drop foot appears adequate to support use of the procedure provided that normal arrangements are in place for clinical governance, consent, and audit. There is a large volume of evidence for FES in drop foot of various neurological origins, though much of it is of low quality (e.g. non-randomised studies, no control groups, short follow up, small patient numbers) however the difficulty in designing and undertaking a randomised controlled trial due to the nature of the intervention, was acknowledged. New data since the last review include the Functional Ambulation: Standard Treatment Versus Electrical Stimulation Therapy (FASTEST) trial, which was a randomized, controlled, single blinded study of 197 patients in the chronic phase of stroke recovery. It is the only trial to date which has directly compared FES with AFO. The results showed no significant difference between the two patient groups.
Safety	In the FASTEST trial, a total of 160 adverse events (AEs) in 59 patients were thought to be related to FES use. Mild AEs accounted for 92% of those, with the other 8% being rated as moderate. 18 serious AEs occurred, but they were unrelated to FES use. Half of the reported AEs were skin irritation caused by stimulation, which were all reversible. Falls relating to the device

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	occurred on 24 occasions. The group considered that orthotic FES presented an acceptable safety profile with a low risk of serious adverse events.
Patient Perspective	Some patients whose needs are not met using AFO and physiotherapy appear to benefit from the use of FES. FES appears to be well tolerated. Other patient reported improvements include: a reduction in falls as recorded by a patient falls diary and users feel their walking requires less effort which enables them to walk further and for longer.
Cost analysis summary	Whilst there have been several cost effectiveness analyses presented at conferences, there are no fully published, independent economic assessments in the medical literature. No cost effectiveness studies assess the costs of FES as a subsequent treatment to AFO, in line with their place in therapy according to UK guidance. A rough estimate of the total cost of skin-surface FES over five years is estimated at about £3680. A significant proportion of the cost of FES would be incurred in the first year of treatment and therefore cost-effectiveness would improve over time with longer duration of use. The aim of the supply and support of the use of FES is to reduce the incident of falls within a vulnerable patient group, therefore reducing the potential hospital admissions associated with this.
Financial impact PbR: In-tariff	FES is associated with modest overall costs, requiring larger up-front hardware costs, some on-going hardware costs, and a significant number of clinic visits, especially in the first year. It was however noted that the number of patients meeting the criteria for FES are small, with 20 new funding requests in 2013/14 for the NTAG region. This would cost approximately £73,600 over five years across the North East and Cumbria.