

9.1 Cerebellar stimulator implants

This commissioning responsibility has transferred to NHS England

(<http://www.england.nhs.uk/>).

Queries around treatment availability and eligibility, as well as referrals and applications for funding should be directed to NHS England.

9.2 Chronic fatigue syndrome (inpatient treatment of)

Category

Not routinely funded

Background

Chronic fatigue syndrome causes persistent fatigue (exhaustion) that affects everyday life and does not go away with sleep or rest. Exactly what causes chronic fatigue syndrome is unknown.

Policy

Patients should be referred to the local Chronic Fatigue Service provided by Kent and Medway NHS and Social Care Partnership Trust. Inpatient treatment is not routinely funded.

9.3 Closure of patent foramen ovale for migraine

Category

Not routinely funded

Background

The foramen ovale is a hole in the wall that divides the two upper chambers of the heart. The hole is present in the heart of a developing foetus, but normally closes up soon after the baby is born. If it fails to close it is known as a patent foramen ovale (PFO). In most people, this does not cause any problems, but some studies have suggested that there could be a link between having a PFO and recurrent migraines. Closure of PFO involves passing a device through a large vessel in the groin up into the heart and closing/blocking the hole in the wall of the heart.

Policy

This procedure is not routinely funded.

Rationale

According to [NICE IPG370](#), current evidence on the efficacy of percutaneous closure of PFO for recurrent migraine is inadequate in quality and quantity. The evidence on safety shows a small incidence of well-recognised but sometimes serious adverse events, including device embolisation and device prolapse.

9.4 Functional electrical stimulation (FES)

Category

Restricted (prior approval required)

Background

Functional electrical stimulation (FES) involves stimulation of the peripheral nerves that supply the paralysed muscle using electrodes that may be implanted or placed on the surface of the skin. The aim is to restore muscular function. FES is used to treat the effects of upper motor neurone lesions that can result from conditions such as stroke, cerebral palsy, multiple sclerosis or spinal cord injury, but may also occur in other conditions. FES is not normally suitable for patients with lower motor neurone lesions.

Policy

- FES is available for drop foot of central neurological origin. Patient selection for implantable FES for drop foot of central neurological origin should involve a multidisciplinary team specialising in rehabilitation. Prior approval is required for this procedure (see Appendix A).
- FES is not routinely funded for the treatment of upper limbs.

Rationale

NICE have concluded that more research is needed to establish the clinical and cost effectiveness of electrical stimulation to improve hand/ arm function in people after stroke, and to characterise the clinical profiles of people who will benefit. Whereas, according to [NICE IPG278](#), current evidence on the safety and efficacy (in terms of improving gait) of FES for drop foot of central neurological origin appears adequate to support the use of this procedure for this indication.

9.5 Hand-held transcutaneous vagus nerve stimulation (tVNS) devices (i.e. gammaCore™) for headache in adults

Category

Not routinely funded

Background

gammaCore™ – the only hand-held transcutaneous vagus nerve stimulation (tVNS) device currently available – uses low-voltage electrical currents to stimulate the cervical branch of the vagus nerve without the need for implants or surgery. The exact mechanism of pain relief with tVNS is not fully understood but it is thought to inhibit activation of several structures in the brain identified as part of the pain matrix of headache.

Policy

Hand-held tVNS devices (i.e. gammaCore™) are not routinely funded by Kent and Medway CCGs for the treatment of headache in adults.

NHS England fund gammaCore for cluster headache in certain circumstances. See [NHS England Innovation and Technology Payment Technical Notes](#) for more information on clinical standards, eligibility criteria and reporting. Funding is currently limited to the 2019/20 financial year.

Queries around treatment availability and eligibility, as well as referrals and applications for funding should be directed to NHS England.

Rationale

According to [NICE IPG 552](#) on tVNS for migraine and cluster headache (2016), the evidence on the efficacy of tVNS for the treatment of these conditions is limited in quantity and quality. In addition, the cost-effectiveness of tVNS for headache in a UK NHS setting has not been established.

9.6

Silicone Ankle Foot Orthosis (SAFO) for foot-drop

Category

Not routinely funded

Background

Foot-drop is a gait abnormality characterised by an inability to raise the toes or move the foot upward from the ankle. Foot-drop is a sign of an underlying problem such as a muscle-wasting disease, injury, neuropathy or a brain and spinal cord disorder, including cerebral palsy and stroke. The tip-toe gait that results from foot-drop can lead to stubbing of the toe, tripping and falling.

Foot-drop may be managed by a range of orthoses. An orthosis is an externally applied device used to support, align, prevent or correct deformities or to improve movement in parts of the body. An ankle foot orthosis (AFO) is a brace, usually made of plastic, worn on the lower leg and foot to hold the foot and ankle in the correct position and to correct foot-drop. Silicone ankle foot orthosis (SAFO) is a thin orthosis made of silicone that is put on like a sock and attached by Velcro straps. Unlike an AFO, it generally fits into normal footwear.

Policy

Silicone Ankle Foot Orthosis (SAFO) is not routinely funded by Kent and Medway CCGs for foot-drop for any patient group.

Rationale

No evidence was identified to suggest SAFO should be commissioned for any patient group, including patients at risk of pressure sores, falls or loss of muscle strength. Alternative orthoses are available to patients with foot-drop.

9.7 Single pulse transcranial magnetic stimulation (sTMS) devices (i.e. SpringTMS®) for headache in adults

Category

Not routinely funded

Background

Transcranial magnetic stimulation (TMS) is a non-invasive procedure that aims to treat or prevent migraine episodes. TMS is given using a tabletop or handheld device that delivers a predetermined level of magnetic pulse or pulses to the head. The device is placed on the scalp and either single (sTMS) or repeated (rTMS) magnetic pulses are delivered.

SpringTMS is currently the only hand-held sTMS device available.

Policy

Single pulse transcranial magnetic stimulation devices (i.e. SpringTMS®) are not routinely funded on the local NHS for the treatment of headache in adults.

Rationale

According to [NICE IPG 477](#) on TMS for migraine (2014), the evidence on the efficacy of sTMS for the treatment of migraine is limited in quantity and for the prevention of migraine is limited in both quantity and quality; there is also uncertainty about the safety of long-term or frequent use of TMS. In addition, the cost-effectiveness of sTMS for headache in a UK NHS setting has not been established.