Kent and Medway Policy Recommendation and Guidance Committee
Policy Recommendation

Policy:	**PR 2018-07: Silicone Ankle Foot Orthosis (SAFO) for foot-drop**
Issue date:	**June 2018**

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered national guidance, evidence relating to the clinical- and cost-effectiveness of SAFO, the baseline position, other CCG policies and the views of local specialists. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommends:

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

This policy recommendation will be reviewed when new information becomes available that is likely to have a material effect on the current recommendation.

Clinical Commissioning Groups (CCGs) in Kent and Medway will always consider appropriate individual funding requests (IFRs) through their IFR process.

Supporting documents

NEL Health Policy Support Unit (HPSU) (2018) *Silicone Ankle Foot Orthosis (SAFO) for foot-drop – Scoping report*

Equality Analysis Screening Tool – Silicone Ankle Foot Orthosis (SAFO) for foot-drop (2018).

Key points and rationale

What is foot-drop?
Foot-drop is a gait abnormality characterised by limited or absent dorsiflexion – 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. Because foot-drop is not a condition in itself but a feature of many different conditions, it is difficult to determine accurate prevalence estimates.

How is foot-drop managed?
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. Other types of ankle foot orthosis include:

- Silicone ankle foot orthosis (SAFO) – the subject of this policy recommendation – 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 and can also be worn with slippers and sandals or even barefoot for the benefit of showering and swimming.
- Pressure relieving ankle foot orthosis (PRAFO) – may be indicated for patients with impaired mobility of the foot and ankle who are at risk of pressure sores.
- Foot-Up – an ankle brace and shoe insert that are linked by a connector with sufficient tension to support dorsiflexion.

Other treatments for foot-drop include: physiotherapy (to strengthen the foot, ankle and lower leg muscles), electrical nerve stimulation (to trigger muscle contraction during walking to correct the gait), and surgery. Surgical options include repairing or grafting nerves, alteration of tendon position, or fusion of the foot and ankle bones.

What does national guidance say?
NICE clinical guidelines (CG) recommend considering orthoses for some children and young people aged under 19 with spasticity (CG145) and adults with gait abnormalities following stroke (CG162). No NICE publications refer specifically to silicone ankle foot orthosis.

What is the baseline position?
Currently, Kent and Medway CCGs do not have a policy on funding of SAFO. According to commissioners, the provision of ankle foot orthoses is supplied through a block contract. A number of individual funding requests (IFRs) have recently been received for SAFO. There are two types of SAFO model, priced at £462 and £655 respectively for a 'junior' model, and £535 and £750 respectively for the adult model. The company suggests that the average lifespan of a SAFO is 2-3 years.

What does the evidence say?
Systematic evidence reviews were undertaken to determine the clinical- and cost-effectiveness of SAFO, and any factors that predict the outcome of using SAFO. The only relevant evidence identified was a single pilot randomised cross over trial of eight patients with Charcot-Marie-Tooth disease. Compared to the AFO, the SAFO was associated with less pain and greater comfort, but there were practical difficulties with SAFO use, such as the effects of heat and sweating. Walking speed was greatest with the AFO. There were no significant differences between the groups in the modified Nottingham Extended Activities of Daily Living Score or the number of pressure ulcers developing. However the study was too small to draw meaningful conclusions.

What is the rationale for PR2018-07?
An evidence review found no evidence 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.

Change sheet

Reason for review:
Currently, Kent and Medway CCGs do not have a policy on funding of silicone ankle foot orthosis (SAFO). A number of individual funding requests (IFRs) have recently been received for SAFO.

Change from baseline position:
No change; SAFO are currently not commissioned by Kent and Medway CCGs.

Estimated cost impact of implementing PR2018-07:
Cost neutral; SAFO are currently not commissioned by Kent and Medway CCGs.