GREATER MANCHESTER EFFECTIVE USE OF RESOURCES (GM EUR) POLICIES:

a) FUNCTIONAL ELECTRICAL STIMULATION (FES) FOR DROP FOOT

b) TROPHIC ELECTRICAL STIMULATION (TES) FOR FACIAL Palsy

Report Summary:

Greater Manchester Shared Services (GMSS) develops policies on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester. In creating policies GMSS reviews clinical conditions and the options for its treatment. It considers the place of treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients (including how any benefit is balanced against possible risks), and whether it represents the best use of NHS resources.

The policies presented today aims, to specify the conditions under which Functional Electrical stimulation (FES) for Foot Drop and Trophic Electrical Stimulation (TES) for Facial Palsy will be routinely commissioned by Clinical Commissioning Groups in Greater Manchester to meet the following objectives:

- To reduce the variation in access to Functional Electrical Stimulation (FES) and Trophic Electrical Stimulation (TES)
- To ensure that FES and TES is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness
- To reduce unacceptable variation in the commissioning of FES and TES across Greater Manchester
- To promote the cost-effective use of healthcare resources.

Recommendations:

That the Single Commissioning Board (SCB) agree to the adoption of the Greater Manchester wide policies for:

- Functional Electrical Stimulation (FES) for Drop Foot
- Trophic Electrical Stimulation (TES) for Facial Palsy

Financial Implications:

Greater Manchester Shared Services Policy Team have provided a Financial Implications Report based on the predicted activity for Tameside and Glossop.

** Data used was the latest available when this policy was finalised 01/04/14 – 21/12/15.

FES - Population data and epidemiology taken from the Stroke Association and the UKGP database indicates that there will be
an estimated 461 new cases of Stroke & MS in Tameside and Glossop and of those there will be 5 patients requiring Functional Electrical Stimulation (FES) for foot drop.

The cost of the basic FES device is £1,490 plus an annual maintenance cost of £300 equating to a total cost per new case of £1,790.

This indicates that the potential financial implication to NHS Tameside and Glossop CCG of adopting this policy would be 5 x £1,790 = £8,950.

There will be potential savings in reducing falls and increasing independence for those needing FES. (No current estimates available).

TES - Population data and epidemiology taken from patient.co.uk indicates that there will be an estimated 66 new cases of facial palsy and of those there will be 4 requiring Trophic Electrical Stimulation (TES).

The cost of 12 months treatment with TES £1,635 with an additional £145 assessment fee equating to a total cost per new case of £1,780.

This indicates that the potential financial implication to NHS Tameside and Glossop CCG of adopting this policy would be 4 x £1,780 = £7,120.

There will be potential savings related to the current treatment needed for the sequelae e.g. dry eye medication, surgical interventions to release muscles and Botox injections to improve symmetry of the face.

(No current estimates available)

Legal Implications: (Authorised by the Borough Solicitor)

These Greater Manchester Effective Use of Resources policies have been ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification. In order to reduce health inequalities, raise standards and tackle financial shortfall it has been agreed that these policies will be consulted upon and agreed at GM level – this report is to enable formal ratification of process already involved in.

How do proposals align with Health & Wellbeing Strategy?

The objectives of these policies (see report summary) support the vision of the Health & Wellbeing Strategy below:

Creating the right care model so that people with long term conditions are better supported and equipped with the right skills to look after themselves and manage their conditions more effectively, reducing dependency on the health and social care system by promoting independence and targeting our resources towards evidence based and cost-effective care, optimising both outcomes and value for money.
How do proposals align with Locality Plan?
The objectives of these policies (see report summary) support the vision of the locality plan below:

To significantly raise healthy life expectancy (HLE) in Tameside and Glossop through a place based approach to better prosperity, health and wellbeing and to deliver a clinically and financially sustainable local health and social care economy within five years.

How do proposals align with the Commissioning Strategy?
The objectives of these policies (see report summary) aligns to the vision of the Commissioning Strategy below:

Creating the right care model so that people with long term conditions are better supported and equipped with the right skills to look after themselves and manage their conditions more effectively, reducing dependency on the health and social care system by promoting independence.

Recommendations / views of the Professional Reference Group:
On 11 May 2016 recommended to adopt GM wide policies without further comment.

Public and Patient Implications:
These commissioning policies have been produced in order to provide and ensure equity, consistency and clarity in the commissioning of Functional Electrical Stimulation (FES) for Drop Foot and Trophic Electrical Stimulation (TES) for facial palsy by Clinical Commissioning Groups in Greater Manchester.

Quality Implications:
Functional Electrical Stimulation (FES) for drop foot - adheres to the guidance in National Institute for Health and Care Excellence (NICE) Interventional Procedures Guidance (IPG) 278

Trophic Electrical Stimulation (TES) for Facial Palsy – NICE have not currently issued guidance on this treatment. Evidence used to support this treatment was taken from:

Cochrane Database for Systemic Reviews
Physical therapy for Bell's palsy (idiopathic facial paralysis) and

And

Medline / Open Athens
Comprehensive facial rehabilitation improves function in people with facial paralysis: a 5-year experience at the Massachusetts Eye and Ear Infirmary

How do the proposals help to reduce health inequalities?
In developing policy the GMSS Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

What are the Equality and Diversity implications?
An Equality Analysis has been carried out on the policies by GMSS.
What are the safeguarding implications? None identified

What are the Information Governance implications? None Arising.

Has a privacy impact assessment been conducted? None

Risk Management: The identified risk would be if the recommendation is to not adopt the GM wide policies as Tameside and Glossop would be creating a possible inequality in accessing health care services for our residents.

NHS Tameside and Glossop CCG would also be required to develop their own policy around Functional Electrical Stimulation (FES) for Drop Foot and Trophic Electrical Stimulation (TES) for Facial Palsy.

Access to Information: The background papers relating to this report can be inspected by contacting:

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Greater Manchester Shared Services (GMSS) has developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission Functional Electrical Stimulation (FES) in accordance with the criteria outlined in this document.

In creating this policy GMSS has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

1. **Introduction**

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity in the commissioning of Functional Electrical Stimulation (FES) services by Clinical Commissioning Groups in Greater Manchester. When this policy is reviewed all available additional data on outcomes will be included in the review and the policy updated accordingly.

FES has a number of applications not all of which have a sound body of evidence to support their routine use. This policy aims to target the resource available for this intervention to those patients where there is evidence that they will benefit the most from the intervention.

2. **Definition**

Functional Electrical Stimulation (FES) is a treatment using small electrical charges to improve mobility in a number of conditions.

There is a reasonable body of evidence and it is recognised as cost effective for foot drop of central neurological and of upper motor neurone origin – it is used mostly for foot drop following stroke or in Multiple Sclerosis.

Dropped foot occurs when damage to nerve pathways means someone experiences weakness or poor coordination in their leg or ankle which affects the way that they walk. Dropped foot leads to a way of walking that requires more effort and uses more energy. The foot may drag along the ground or the toes hang down when walking, which makes the individual more vulnerable to tripping and falling. People may alter the way that they walk to compensate, commonly lifting their leg higher. In time, this can lead to further problems such as pain in the hips or lower back, a tightening of muscles and poor balance.

Several different FES devices are available. Each has a control box, about the size of a pack of cards, which is either worn on the leg or at the waist. The devices apply impulses through electrodes attached to the skin. A version is also available that uses a surgically implanted nerve stimulator. These work by replacing the stimulation normally received from the brain to the muscles controlling the position of the foot resulting in a basic but useful movement.

The device is activated by a pressure sensitive switch in the shoe. When the foot is lifted, an impulse is applied causing the foot to tilt to the correct angle. When the foot is placed on the ground again, pressure is reapplied to the switch and the impulse ceases.

3. **Aims and Objectives**
Aim
This policy document aims to specify the conditions under which Functional Electrical stimulation (FES) will be routinely commissioned by Clinical Commissioning Groups in Greater Manchester.

Objectives
• To reduce the variation in access to Functional Electrical stimulation (FES).
• To ensure that Functional Electrical stimulation (FES) is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
• To reduce unacceptable variation in the commissioning of Functional Electrical stimulation (FES) across Greater Manchester.
• To promote the cost-effective use of healthcare resources.

4. Criteria for Commissioning

Mandatory Criteria
The patient must be being treated for foot drop which must be of central neurological origin, due to an upper motor neurone lesion i.e. one that occurs in the brain or spinal cord at or above the level of T12. This is normally but not exclusively associated with spasticity.
Upper motor neurone lesions resulting in dropped foot occur in conditions such as stroke, multiple sclerosis, incomplete spinal cord injury at T12 or above, cerebral palsy, familial/hereditary spastic paraparisis and Parkinson's disease.

In some cases wireless FES devices may be required if this is the case then the application form should contain all relevant information for checking against the criteria in Appendix 2.

Policy Exclusions
Other forms of electrical stimulation e.g. Percutaneous Electrical Nerve Stimulation (PENS) and Transcutaneous Electrical Nerve Stimulation (TENS) for conditions other than foot drop are not covered by this policy.

Clinicians can submit an Individual Funding Request (IFR) if they feel there is a good case for exceptionality.

Exceptionality means ‘a person to which the general rule is not applicable’. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:

• Significantly different to the general population of patients with the condition in question.

and as a result of that difference

• They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

History of this paper:

• Greater Manchester Effective Use of Resources Steering Group, 8 July 2015 - Approved
• Greater Manchester Chief Finance Officers, virtually during April 2016 - Approved
• Greater Manchester Heads of Commissioning, virtually during April 2016 - Approved
• Greater Manchester Association Governing Group, 3 May 2016 - Approved
POLICY SUMMARY - Trophic Electrical Stimulation (TES) for Facial Palsy

Greater Manchester Shared Services (GMSS) has developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission Trophic Electrical Stimulation (TES) for Facial Palsy in accordance with the criteria outlined in this document.

In creating this policy GMSS has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

5. Introduction

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity in the commissioning of trophic electrical stimulation for facial palsy by Clinical Commissioning Groups in Greater Manchester. When this policy is reviewed all available additional data on outcomes will be included in the review and the policy updated accordingly.

Trophic electrical stimulation is a treatment aimed at restoring the function of the muscles of the face through mimicking the stimulation provided from the normal nerve functioning.

The majority of facial palsies that are idiopathic or infective will resolve spontaneously – usually within 3 months.

This policy has been developed to target this resource at those cases where there is residual weakness after the normal period when resolution would be expected or where there is traumatic damage to the nerve e.g. from surgery to remove a tumour of the face.

It is targeted at those patients where there are functional issues including inability to effectively close their eyes, difficulty speaking and difficulty eating.

6. Definition

Facial Palsy / Paralysis

Facial palsy refers to weakness of the facial muscles, resulting from temporary or permanent damage to the facial nerve.

When a facial nerve is either non-functioning or missing, the muscles in the face do not receive the necessary signals in order to function properly. This results in paralysis of the affected part of the face, which can affect movement of the eye(s) and/or the mouth, as well as other areas.

There are different degrees of facial paralysis: sometimes only the lower half of the face is affected, sometimes one whole side of the face is affected and in some cases both sides of the face are affected.

The face sags and is drawn across to the opposite side on smiling. Voluntary eye closure may not be possible and can produce damage to the conjunctiva and cornea. In partial paralysis, the lower face is generally more affected. In severe cases, there is often demonstrable loss of taste over the front of the tongue and intolerance to high-pitched or loud noises. It may cause mild dysarthria and difficulty with eating. The most common system used for describing the degree of paralysis is the House-Brackmann scale, where 1 is normal power and 6 is total paralysis. It is important to
identify whether the patient has an upper motor neurone (UMN) or lower motor neurone (LMN) lesion, to assist in identifying the cause.

**Trophic Electrical Stimulation**

Electrical stimulation has been widely used over the years and is known to help certain nerve muscle problems. Initial stimulation techniques focused on making the muscle move with the electrical impulses hoping that this would promote recovery (Faradism), with new advances in technology it is now possible to embark on a more specific conditioning of the system involved.

Electrical stimulation is a treatment offered for a number of nerve muscle related problems such as Bell's Palsy and other forms of facial paralysis. Trophic Electrical Stimulation (TES) can be applied to muscles to promote the uptake of fresh blood supply. By providing the right nutrition, growth occurs. The treatment provides a way of warming up the muscle, targeting the deep red base layers, the first to deteriorate where a nerve supply has been disrupted. Unlike beauty machines TES rebuilds the deeper muscle fibres promoting long lasting results.

### 7. Aims and Objectives

**Aim**

This policy document aims to specify the conditions under which trophic electrical stimulation for facial palsy be routinely commissioned by Clinical Commissioning Groups in Greater Manchester.

**Objectives**

To reduce the variation in access to trophic electrical stimulation for facial palsy.

To ensure that trophic electrical stimulation for facial palsy is commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.

To reduce unacceptable variation in the commissioning of trophic electrical stimulation for facial palsy across Greater Manchester.

To promote the cost-effective use of healthcare resources.

### 8. Criteria for Commissioning

**Mandatory Criteria**

Chronic idiopathic facial palsy (Bell's palsy) which has not responded to treatment in 6 months with steroids (usually prednisolone); eye care measures and possible referral to physiotherapy (this would be optional rather than mandatory) or for cases of recurrent idiopathic facial palsy (Bell's palsy)

**OR**

Cases of nerve damage where the specialist managing the case has provided evidence in support of referral for trophic electrical stimulation (evidence should include the cause of the nerve damage; treatment tried to date and outcomes for each one tried; functional issues associated with the damage; expected outcomes from TES.)

**AND**

Where there are demonstrable functional problems associated with the palsy including but not restricted to:
- difficulty closing the eye
- difficulty articulating speech
- difficulty in eating and drinking
- difficulty with facial expressions sufficient to interfere with non-verbal communication

### History of this paper:

- Tameside & Glossop Clinical Commissioning Group – Planning Implementation and Quality (PIQ) meeting, 10th June 2015 – DRAFT Approved
- Greater Manchester EUR Steering Group, 8 July 2015 - Approved
- Greater Manchester Chief Finance Officers, virtually during April 2016 - Approved
- Greater Manchester Heads of Commissioning, virtually during April 2016 - Approved
- Greater Manchester Association Governing Group, 3 May 2016 – Approved
- Tameside and Glossop Clinical Commissioning Group - Patient Reference Group (PRG) meeting, 11 May 2016 – Recommendation to adopt