Introduction

This policy review is part of a wider project to review and update more than 100 health policies by six Clinical Commissioning Groups (CCGs) in Merseyside. The review will ensure that the latest clinical guidance is applied consistently across Merseyside and that patients have access to the latest treatments.

Name of treatment or procedure

Botulinum toxin A and B (Botox)

Description of treatment or procedure

Botulinum toxin is a protein produced by clostridium botulinum bacteria and related species. When injected into the body it affects the nervous system and it can be used to treat a number of disorders that cause excessive or abnormal muscle movement. These include spasticity that results from a stroke or a spinal cord injury, and spasms in the head and neck, eyelid, vagina, limbs, jaw or vocal cords. Botox can also be used to relax clenched muscles (for example, when people grind their teeth in their sleep) and to correct eye alignment ("crossed eyes").

Types A and B are used to treat conditions including upper motor neurone syndrome, localised excessive sweating, involuntarily closed eyes and chronic migraine. It is also widely used in cosmetic treatments. A number of botulinum toxin type A products are commercially available (including Botox®, Dysport®, Xeomin®). Other brands are available but are only licensed for cosmetic procedures (Allergan).

Current policy

Botulinum toxin type A is only routinely available for the following conditions and circumstances:

- Anal fissures (a maximum of two courses of injections), where standard treatment has been tried for at least two months and hasn't worked
- Blepharospasm (tightly closed eyelids) and hemifacial spasm (involuntary muscle contractions in the face)
- Probable joint contraction in multiple sclerosis (MS), in conjunction with prolonged stretching modalities
- Focal dystonia (localised muscle contractions), where other measures are inappropriate or haven't worked
- Focal spasticity in patients with upper motor neurone syndrome, cerebral palsy, stroke, acquired brain injury, MS, spinal cord injuries or neurodegenerative disease, where other measures are inappropriate or haven't worked
- Idiopathic cervical dystonia, also called spasmodic torticollis (involuntary muscle contractions in the neck)
- To manage headaches in adults with chronic migraine (defined as headaches on at least 15 days per month, at least eight days of which are with migraine) that has not responded to at least three prior drug therapies, and whose condition is appropriately managed to avoid over-use of medicines
- Refractory detrusitor overactivity (overactive bladder), where conservative therapy and conventional drug treatment have not controlled symptoms

- Sialorrhoea (excessive drooling), when all other treatments have failed.

Botulinum toxin type B is not routinely available.

Proposed changes

As now, botulinum toxin type A will not be routinely available for non-axillary hyperhidrosis (excessive sweating outside the armpit area). However, it is now recommended as a treatment option in patients with severe axillary hyperhidrosis (excessive underarm sweating) that has not been adequately controlled by topical aluminium chloride or other extra-strength antiperspirants. 'Severe' hyperhidrosis is defined as having a HDSS score of 3 or 4. This brings the proposed policy in line with the Pan Mersey Area Prescribing Committee (APC) position on the use of botulinum toxin A for treating severe axillary hyperhidrosis.

Botulinum toxin type A should not be used to treat migraines where a patient's condition is not responding well to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles), or it has changed to episodic migraine (fewer than 15 headache days per month) for three consecutive months. When it is prescribed and administered, this will be done under the supervision of a specialist designation neurological centre. The criteria itself has not changed, but in the revised policy document this content and layout have been updated to reflect NICE TAG260 more clearly.

Reason for proposed changes

- See NICE Technology Appraisal 159 relating to the treatment of hyperhidrosis in people with social anxiety disorder: https://www.nice.org.uk/guidance/cg159
- See Pan Mersey Area Prescribing Committee (APC) Prescribing Policy Statement relating to the treatment of severe axillary hyperhidrosis: http://www.panmerseyapc.nhs.uk/recommendations/documents/PS145.pdf?UNLID=89963070920171024181622
- See NICE Technology Appraisal 260 relating to the treatment of migraines: https://www.nice.org.uk/guidance/ta260

Summary of proposed changes

- The policy for Botulinum toxin A and B is being aligned with the Pan Mersey Area Prescribing Committee (APC) for the treatment of anal fissures and Axilliary Hyperhidrosis which have been in place for a number of years.
- The policy remains aligned with NICE TA260 for Migraine.
- The revised policy remains aligned with the current policy for the following conditions:
    - Blepharospasm and hemifacial spasm
    - Probable contracture of joint in multiple sclerosis
    - Focal dystonia
    - Focal spasticity in patients with upper motor neurone syndrome
    - Idiopathic cervical dystonia
    - Refractory detrusitor overactivity
    - Sialorrhoea (excessive drooling).
- Those who have severe axillary hyperhidrosis (excessive underarm sweating) may now be eligible for botox treatment.

- Those who have migraines may no longer be eligible for botox treatment if their condition is not responding to it well enough.