Guidance on use of botulinum toxin in Greater Manchester – version 3.0 – January 2020
1. Introduction

Botulinum toxin is a tariff-excluded high cost drug used widely by the secondary and tertiary care specialists for non-aesthetic indications. Many of those indications are off-label and there is a lack of national or local guidance for such uses. Typically, where there is no national or local policy or guidance, and a tariff excluded high cost drug is used outside of specified criteria, the intervention requires funding approval via the Greater Manchester Effective Use of Resources process and an individual funding request submission, prior to commencing the treatment. However, it is acknowledged that only a small proportion of interventions with botulinum toxin follow this process.

The spend on botulinum toxin across Greater Manchester (GM) in 2018/19 amounted to nearly £1.7m\(^1\) and contributed to 1.8% of the total CCG commissioned tariff excluded high cost drugs budget.

2. Purpose

The purpose of this guideline is to support standardised approach to availability of botulinum toxin within the NHS in GM and allow transparency in the management of this drug in evidence based and cost effective manner. The approach is pragmatic and recognises the widespread use of botulinum toxin in many specialties and the fact that treatment may continue long term. This guidance was written following review of available evidence and extensive consultations with GM clinicians representing specialities where botulinum toxin is employed in patient care. A clear set of criteria has been listed for each recommended indication.

3. Recommendations and criteria

3.1. Botulinum toxin treatment is **not available** on the NHS in GM for the treatment of facial ageing, wrinkle correction, or any other solely aesthetic indication.

3.2. People whose treatment with botulinum toxin is outside of this guidance, but was started within the NHS before this policy was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

3.3. Where specified and for all indications not contained in this document, the use of botulinum toxin is not recommended.

3.4. Currently the funding mechanism for botulinum toxin is monitored approval. The providers should agree with commissioners on the method of demonstrating ongoing compliance with this guidance.

3.5. This guidance considers patients treated in adult services unless otherwise specified.

3.6. The table below lists uses of botulinum toxin and provides initiation criteria that patients should meet to obtain the treatment. Continuation criteria (including continuation of care for patients transferred form paediatric services) must be met for further injections and include documented evidence indicating that the patient is responding to and remaining to benefit from the treatment with botulinum toxin. Where applicable, other continuation and discontinuation criteria are stated in the table.

\(^1\) BI tool, HCD report, GM JCT, accessed on 13/08/2019. GM patients treated by NHS providers only. No data for private providers.
### A. Spasticity

<table>
<thead>
<tr>
<th>1a</th>
<th>Focal spasticity in adults</th>
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<tbody>
<tr>
<td></td>
<td>Botulinum toxin can be used for focal spasticity due to stroke or other neurological illness (e.g. multiple sclerosis, cerebral palsy, motor neurone disease), and trauma of brain or spinal cord, where:</td>
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<tr>
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<td>(1) there is focal element to spasticity, and</td>
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<td>(2) spasticity is interfering with function or independence (e.g. mobility, communication, nutritional intake) and/or is painful, and</td>
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<td></td>
<td>(3) treatment is conducted by suitably experienced team (e.g. neuro-rehabilitation team, including consultant with appropriate skills and training), and</td>
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<td>(4) treatment goals and outcome measures are agreed and documented before treatment starts.</td>
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<tr>
<th>1b</th>
<th>Spasticity in children</th>
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<td></td>
<td>NHSE commissioned. Follow NHSE process for funding approval.</td>
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### B. Movement disorders - including focal dystonias and facial nerve disorders

<table>
<thead>
<tr>
<th>2</th>
<th>Upper limb dystonia</th>
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<tr>
<td></td>
<td>Botulinum toxin can be used for focal upper limb dystonia of idiopathic origin (e.g. writer's cramp), or secondary to a neurodegenerative disorder (e.g. fixed elbow extension or shoulder retraction due Parkinson’s disease or progressive supranuclear palsy) where:</td>
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<td>(1) dystonia is interfering with function or independence (e.g. mobility, communication, nutritional intake) and/or is painful, and</td>
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<td>(2) other methods have not been successful or were not appropriate (e.g. physiotherapy, pharmacological treatment), and</td>
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<td>(3) treatment is conducted by suitably experienced team (e.g. neuro-rehabilitation team, including consultant with appropriate skills and training), and</td>
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<td>(4) treatment goals and outcome measures are agreed and documented before treatment starts.</td>
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<th>3</th>
<th>Lower limb dystonia</th>
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<tr>
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<td>Botulinum toxin can be used for lower limb dystonia, primary or secondary to a neurodegenerative disease (e.g. Parkinson’s disease, or progressive supranuclear palsy) where:</td>
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<td>(1) dystonia is interfering with function or independence (e.g. mobility) and/or is painful, and</td>
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<td>(2) other methods have not been successful or were not appropriate (e.g. physiotherapy, pharmacological treatment), and</td>
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<td>(3) treatment is conducted by suitably experienced team (e.g. neuro-rehabilitation team, including consultant with appropriate skills and training), and</td>
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<td>(4) treatment goals and outcome measures are agreed and documented before treatment starts.</td>
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<td>Condition</td>
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<td>4</td>
<td>Spasmodic torticollis</td>
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<tr>
<td></td>
<td>(cervical dystonia)</td>
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<td>5</td>
<td>Laryngeal dystonia</td>
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<td></td>
<td>(spasmodic dysphonia)</td>
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<td>6</td>
<td>Cricopharyngeal dysfunction</td>
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<td>7</td>
<td>Palatal myoclonus</td>
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<td>8</td>
<td>Oromandibular dystonia</td>
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<td>9</td>
<td>Blepharospasm</td>
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<td>10</td>
<td>Meige's syndrome</td>
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(3) patient has functional issues - pain or spasm and disfigurement, difficulties with vision, feeding, or impaired dental care or malocclusion preventing from swallowing or impairing speech.

| 11 | Hemifacial spasm | Botulinum toxin can be used for hemifacial spasm, where  
(1) there is evidence of functional and/or visual impairment. |
| 12 | Post facial nerve palsy - hyperkinesis causing asymmetry and synkinesis | Botulinum toxin can be used for patients with chronic, unresolved facial nerve palsy resulting in asymmetry and/or synkinesis, where:  
(1) there is evidence of functional impairment (e.g. communication, nutrition, pain due to disfigurement), and  
(2) permanent nerve damage cannot be managed by facial rehabilitation alone, and  
(3) where surgery not indicated or unsuccessful.  
Continuation criteria:  
(1) patient must still show functional issues returning after previous successful intervention with botulinum toxin. |

Botulinum toxin is **not available** solely for appearance enhancement.

### C. Ophthalmic disorders

| 13 | Crocodile tears syndrome | Botulinum toxin can be used for severe gustatory lacrimation, where:  
(1) symptoms cause functional problems, and  
(2) other conservative treatment (e.g. trigger avoidance) was not appropriate or ineffective. |
| 14 | Prevention of corneal exposure (protective ptosis) | Botulinum toxin can be used for induction of temporary protective ptosis to prevent or allow corneal healing, where:  
(1) eye lubrication or contact lenses are insufficient or not tolerated, and  
(2) patient is unsuitable for tarsorrhaphy, or  
(3) tarsorrhaphy alone can result in complications.  
Discontinuation criteria:  
Stop once corneal healing achieved or prevention no longer needed. |
<p>| 15 | Dystonic brow spasm | Not recommended. There is insufficient evidence to support use of botulinum toxin for dystonic brow spasm. |</p>
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<th>Page</th>
<th>Section</th>
<th>Description</th>
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| 16   | Epiphora | Botulinum toxin can be used as an alternative to surgery for patients with epiphora who:  
(1) have documented functional issues, and  
(2) are unsuitable for surgery (e.g. elderly or previous ophthalmic malignancy). |
| 17   | Spastic entropion | Botulinum toxin can be used for unresolving entropion where:  
(1) there is risk of damage to vision (e.g. corneal ulcer or ketatopathy secondary to entropion), and  
(2) where surgery is inappropriate or unlikely to resolve the issue as a single intervention. |
| 18   | Nystagmus | Not recommended. There is insufficient evidence to support use of botulinum toxin for nystagmus, and on evidence available, the side effects appear to outweigh benefits. |
| 19a  | Squint (strabismus) - adults and children – diagnostic | A single dose of botulinum toxin per eye can be used as diagnostic intervention to evaluate risk of making double vision worse or demonstrate potential for binocular vision, where:  
(1) prism adaptation test predicts post-operative diplopia, to evaluate risk of making double vision worse or demonstrate potential for binocular vision.  
**Note strabismus repair is considered aesthetic in adults with uncorrected congenital strabismus and no potential for binocular vision (no binocular fusion). Botulinum toxin is not available solely for appearance enhancement.** |
| 19b  | Squint (strabismus) - adults and children – therapeutic | Botulinum toxin can be used for strabismus in children and adults, where:  
(1) there is potential for binocular vision, such as acute onset esotropia, sixth nerve palsy and infantile esotropia, and  
(2) conservative treatment (prisms and/or exercises) fail, or  
(3) for medical management of cases unsuitable for surgery - e.g. where patient is not suitable for surgery for a clinical reason.  
**Note strabismus repair is considered aesthetic in adults with uncorrected congenital strabismus and no potential for binocular vision (no binocular fusion). Botulinum toxin is not available solely for appearance enhancement.** |
| 20   | Decompensating esophoria and decompensating exophoria | Botulinum toxin can be used for decompensating heterophoria (esophoria or exophoria), where:  
(1) the patient is symptomatic, asymptomatic with foveal suppression or likely to decompensate and lose binocularity, and  
(2) there is record of functional and visual impairment, and  
(3) other treatments have been tried and failed (removal of environmental factors, correction or modification of refractive errors, orthoptic exercises, prisms), and  
(4) surgery is inappropriate or patient is unsuitable for surgery.  
**Botulinum toxin is not available solely for appearance enhancement.** |
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<td><strong>D. Gastrointestinal tract disorders</strong></td>
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| **21** | **Salivary fistulas** | Botulinum toxin can be used for unresolving salivary fistulas, where:  
(1) discharge is severe and affects daily functioning, and  
(2) conservative methods have been tried and results are not satisfactory, and  
(3) fistula is refractory to surgical revision or surgical treatment is not appropriate. |
| **22** | **Sialocele** | Botulinum toxin can be used for unresolving sialoceles, where:  
(1) daily functioning is affected (e.g. pain, difficulties with eating, speaking),  
(2) conservative methods have been tried and results are not satisfactory, and  
(3) fistulae refractory to surgical revision or surgical treatment is not appropriate |
| **23** | **Sialorrhea (NICE TA605, Xeomin)** | Botulinum toxin can be used for sialorrhea under following circumstances:  
(1) Sialorrhea is not drug induced.  
(2) Sialorrhea is causing functional impairment, and/or patient is at risk of aspiration (e.g. intubation), and  
(3) Systemic agents have been tried and failed (min 2 drugs), or were contraindicated, not tolerated, or not appropriate due to co-morbidities, and  
(4) botulinum toxin is administered with ultrasound guidance unless otherwise advised by local protocol. |
| **24** | **Achalasia** | Botulinum toxin can be used for patients with achalasia who are:  
(1) at high risk of aspiration, and  
(2) unfit for surgery and,  
(3) at risk from complications from pneumatic dilatation treatment (perforated oesophagus) |
| **25** | **Sphincter of Oddi dysfunction (SOD) type III** | A single dose of botulinum toxin is recommended as a diagnostic trial instead of manometry prior to sphincterotomy only for patients with suspected type III SOD. Repeated injections are not recommended for SOD. |
| 26 | Abdominal wall reconstruction | Botulinum toxin can be used as one-off, preoperative, ultrasound guided injection in elective complex hernia patients where:
(1) major abdominal surgery, separation of muscular components and mesh repair is required, and
(2) abdominal wall defects are greater than 15cm, and
(3) loss of domain is greater than 20%.

| 27 | Anal fissure (single dose) | A single dose of botulinum toxin is recommended for patients meeting the following criteria:
(1) The anal fissure is chronic, and
(2) The following symptoms are present:
(a) pain on defecation and lasting afterwards, and/or
(b) bleeding, and
(3) The following treatments have been tried and were unsuccessful:
(a) bulk fibre supplements +/- stool softeners and adequate fluid intake (min 6-8 weeks), and
(b) added 0.4% GTN ointment (BD for up to 8 weeks) +/- local anaesthetic, or
(c) added 2% diltiazem cream (unlicensed, BD for 8 weeks) - maximum up to two courses if patient initially responding

| 28 | Anismus (pelvic floor dyssynergia) | Botulinum toxin can be used for patients with anismus, where
(1) conservative measures were tried and failed, including:
(a) dietary and lifestyle modification, and
(b) enemas and laxatives, and
(c) biofeedback, and
(d) surgery is inappropriate, and
(2) diagnosis of prolapse was excluded. |
### E. Hyperhidrosis

| 29a | Severe primary hyperhidrosis of the axillae | Botulinum toxin can be used for significant and intractable excessive sweating of axillae, where
(1) hyperhidrosis not associated with social anxiety disorder or secondary to other underlying cause, and
(2) there is a record of unsuccessful trial of:
(a) conservative measures (lifestyle factors and avoidance of triggers), and
(b) aluminium based topical treatment for at least 1-2 months, and
(c) systemic anticholinergic (preferably oxybutynin, off-label), and
(d) iontophoresis. |
| 29b | Severe primary palmar or plantar hyperhidrosis | Botulinum toxin can be used for significant and intractable excessive sweating of the palmar or plantar area:
(1) hyperhidrosis not associated with social anxiety disorder or secondary to other underlying cause, and
(2) there is a record of unsuccessful trial of:
(a) conservative measures (lifestyle factors and avoidance of triggers), and
(b) aluminium based topical treatment for at least 1-2 months, and
(c) systemic anticholinergic (preferably oxybutynin, off-label), and
(d) iontophoresis. |
| 29c | Severe primary craniofacial hyperhidrosis | Botulinum toxin can be used for significant and intractable excessive sweating of craniofacial area:
(1) hyperhidrosis not associated with social anxiety disorder or secondary to other underlying cause, and
(2) there is a record of unsuccessful trial of:
(a) conservative measures (lifestyle factors and avoidance of triggers), and
(b) aluminium based topical treatment for at least 1-2 months, and
(c) systemic anticholinergic (preferably oxybutynin, off-label). |
| 29d | Severe generalised sweating | Not recommended. There is insufficient evidence to support use of botulinum toxin for generalised hyperhidrosis. |
|   | Frey's syndrome | Botulinum toxin can be used for significant and intractable excessive sweating of craniofacial area in Frey's syndrome where:
|   |   | (1) there is a record of unsuccessful trial, history of intolerance or contraindication to:
|   |   | (a) conservative measures (lifestyle factors and avoidance of triggers), and
|   |   | (b) topical aluminium based treatment. |

### F. Oromandibular disorders

|   | Temporo-mandibular joint disorders | Botulinum toxin can be used for people with temporomandibular joint disorder, where
|   |   | (1) symptoms result in functional issues (e.g. spasm and pain, limited mouth opening), and
|   |   | (2) the spasm is localised (not diffuse), and
|   |   | (3) other measures were tried and not helped:
|   |   | (a) non-pharmacological (physiotherapy, restorative dentistry - e.g. occlusal or bite adjustments, bite raising appliances, occlusal stabilisation splints, where relevant), and
|   |   | (b) pharmacological interventions (analgesics, anti-inflammatories, muscle relaxants), and
|   |   | (c) surgery not appropriate. |

|   | Masseteric hypertrophy | Botulinum toxin can be used for masseter hypertrophy, where:
|   |   | (1) symptoms result in pain, spasm or other functional issues (e.g. limited mouth opening or severe facial disfigurement), and
|   |   | (2) other measures were tried and not helped:
|   |   | (a) non-pharmacological (physiotherapy, orthodontic interventions - bite adjustments or teeth splints where relevant), and
|   |   | (b) pharmacological interventions (analgesics, anti-inflammatories, muscle relaxants), and
<p>|   |   | (c) surgery is not appropriate. |</p>
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<td><strong>G. Pain syndromes</strong></td>
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| **33** | Refractory trigeminal neuralgia | Botulinum toxin can be used in patients with refractory trigeminal neuralgia, where:  
1) the condition is refractory to oral pharmacotherapy, and at least 3 oral medications tried and unsuccessful, not tolerated or contraindicated (carbamazepine, and second anticonvulsant and baclofen), and  
(2) surgery is inappropriate. |
| **34** | Prophylaxis of headaches with chronic migraine (NICE TA260, Botox) | Botulinum toxin can be used for chronic migraine, where:  
(1) patient experiences headaches on at least 15 days per month of which at least 8 are with migraine, and  
(2) medication overuse headache has been ruled out (<10 days per month of opiate or triptan use, <15 days/month of other analgesics) where no existing co-morbidities requiring continuous analgesia, or previous withdrawal of analgesics/triptans for 3 months had no effect, and  
(3) other causative disorders have been ruled out, and  
(4) there is a record of a minimum three trials of a pharmacological preventative (unless contraindicated), at a maximum tolerated appropriate doses for at least 3 month each (start and stop dates and reason for discontinuation must be clearly stated). NB This should not include pizotifen or gabapentin.  
Continuation criteria:  
(1) Percentage of reduction (min 30%) in severe and disabling headache days per month after initial 2 treatment cycles, measured over minimum of a month.  
Discontinuation:  
(1) chronic migraine changes to episodic (less than 15 days/month in 3 consecutive months), or  
(2) treatment not effective (max 2 cycles) |
| **35** | Medication overuse headache | Not recommended. There is insufficient evidence to support use of botulinum toxin for medication overuse headache. |
| **36** | Post-craniotomy pain | Not recommended. There is insufficient evidence to support use of botulinum toxin for post-craniotomy pain. |
### H. Bladder dysfunctions

#### 37a Overactive bladder with symptoms of urinary incontinence, urgency and frequency

Botulinum toxin can be used intravesically in patients with overactive bladder, who:

1. have urodynamically confirmed detrusor over activity*
2. have received and not responded to a trial of conservative management including:
   a. lifestyle interventions (adequate fluid intake, reduced caffeine intake, weight management)
   b. appropriate behavioural management programme (e.g. Bladder training lasting at least 6 weeks)
   c. for patients with mixed urinary incontinence pelvic floor muscle training lasting at least 3 month, and
3. received and not responded to drug trials of (unless contra-indicated or not tolerated):
   a. up to two antimuscarinic drugs (min 4 weeks of one drug if effective), and /or mirabegron, or
   b. in post-menopausal women with vaginal atrophy intra-vaginal oestrogen for 3 months
4. are willing and able to self-catheterise, and
5. the clinical suitability was determined by multidisciplinary team (MDT) on basis of symptom severity (patient completed bladder diary over at least 3 days)

**Continuation criteria:**

1. assessed at 3 months and
2. showing a 50% or greater improvement in continence episodes or urgency episodes per day

*unless taking part in the NIHR recognised trial or if the urodynamic test cannot be performed in a female patient, the reasons must be documented and decision to use botulinum toxin must be MDT recommended.

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#### 37b Neurogenic detrusor overactivity with urinary incontinence due to spinal cord disease or injury

Botulinum toxin can be used intravesically to improve bladder storage in patients with spinal subcervical spinal cord injury (traumatic or non-traumatic), or multiple sclerosis, who:

1. have symptoms of overactive bladder, e.g. urinary incontinence, urgency and frequency (urodynamic test is not required)
2. have had considered a behavioural management programme, e.g. timed voiding, bladder retraining or habit retraining, by a healthcare professional with relevant competences and in conjunction education about lower urinary tract function for the patient and carers, and
3. received and not responded to antimuscarinic drug trials of (unless contra-indicated or not tolerated), and
4. are willing and able to self-catheterise, or their carers are able and willing to manage catheterisation regimen.

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Note NHSE commissioned where botulinum toxin used intravesically in spinal cord injury, and patient is treated under recognised MS specialist centre with specialist nurse support. Follow NHSE process for funding approval.
I. **Skin**

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<tbody>
<tr>
<td>38</td>
<td>Scar softening and modification</td>
<td>Not recommended. There is insufficient evidence to support use of botulinum toxin for scar prevention, modification and softening.</td>
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<tr>
<td>39</td>
<td>Leaking (hyperactive) urostomy</td>
<td>Not recommended. There is insufficient evidence to support use of botulinum toxin for leaking (hyperactive) urostomy.</td>
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<td>40</td>
<td>Digital ulceration</td>
<td>NHSE recommended. Use of botulinum toxin requires an IFR submitted to NHSE (outside of their policy).</td>
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4. **Points for consideration:**

4.1. For licensed products, marketing authorisation should be consulted for advice on dosing, frequency and injection sites in order to achieve best clinical outcomes. For off-label uses it is recommended to follow local protocol and up to date published literature. It is advisable to adhere to national guidance where applicable (e.g. NICE).

4.2. Currently there are three licensed botulinum A and one botulinum B brands. These products are not interchangeable, dosing regimens and licensed uses vary. A licensed product should be used as a first choice where possible.

4.3. Electromyography (EMG) and ultrasound guidance (USG) should be used where appropriate (e.g. where muscles cannot be easily palpated) and only by skilled and experienced specialist.

4.4. Where treatment with botulinum toxin does not bring the expected outcomes the following factors should be considered for primary and secondary non-responders:

- dose optimisation
- injection technique modification (e.g. where EMG or USG not used or not used appropriately)
- muscle weakness or atrophy
- changes in pattern of muscle involvement during treatment
- inappropriate reconstitution or storage of product
- misdiagnosis
- immunogenicity (neutralising antibodies currently not routinely tested in GM).

Patients who develop immune-resistance to one serotype of botulinum toxin may benefit from another. Product switching is not covered in this guidance. Local protocols and/or up to date literature should be consulted for such practice.
4.5. MHRA drug safety update

Products that contain botulinum toxin are associated with the risk of serious adverse reactions due to distant spread of toxin. Recommendations include:

- Spread reactions including muscle weakness, dysphagia, and aspiration - these have been reported rarely with all products that contain botulinum toxin.
- Extreme caution is needed on administration of products that contain botulinum toxin to patients who have neurological disorders, or a history of dysphagia or aspiration.
- Only physicians with appropriate experience (including use of the required equipment) should administer products that contain botulinum toxin.
- Patients or caregivers should be informed about the risk of spread of toxin, and should be advised to seek immediate medical care if problems with swallowing or speech develop, or if respiratory symptoms arise.
- Units of botulinum toxin are not interchangeable from one product to another.
- Recommended administration techniques and specific dosing guidance (including the recommendation to use the minimum effective dose and titrate according to individual need) should be followed.

5. Related GM policies and guidelines

EUR: GM Policy Statement: Hyperhidrosis (available on CCGs’ websites, under review at the time of finalising this document)
EUR: GM Headache Disorders Policy (available on CCGs’ websites, under review at the time of finalising this document)
EUR: GM Other Aesthetic Surgery Policy (available on CCGs’ websites, under review at the time of finalising this document)
EUR: GM Surgical Review of Scarring (available on CCGs’ websites)
GMMMG: NW Headache Pathway and Guidance Notes, (available on GMMMG website) http://gmmmg.nhs.uk
GMMMG Treatment of Overactive Bladder in Women Pathway, (available on GMMMG website) http://gmmmg.nhs.uk
NW Neurosciences Partnership – Botulinum Toxin in the Management of Spasticity in Adults (2005)

6. References

- Summaries of product characteristics https://www.medicines.org.uk/emc/
- Cochrane http://uk.cochrane.org/search/reviews/
- NICE https://www.nice.org.uk/guidance
- MHRA Drug safety Update October 2007; Vol 1, Issue 3:10

A complete list of references for each indication is available at a request form GMSS Medicines Optimisation. This includes guidelines, databases review results and other resources.