

Greater Manchester botulinum toxin commissioning policy

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Produced by GMSS. Lead author: Anna Pracz, Advanced Medicines Optimisation Pharmacist.

DOCUMENT CONTROL

Document location

Copies of this document can be obtained from:

Name:	Medicines Optimisation Team
Address:	Greater Manchester Shared Services, GMSS Ellen House, Waddington Street Oldham, OL9 6EE
Telephone:	0161 212 5680

Revision history

The latest and master version of this document is held by the GMSS Medicines Optimisation Team

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31/03/2016	K Griffiths	Consultation comments incorporated	0.2
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Approvals

This document must be approved by the following before distribution:

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HCDSG	Draft version 0.8 approved with minor amendment	24/01/2018	0.9
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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 Effective Use of Resources (EUR) process and Individual Funding Request (IFR) submission, prior to commencing the treatment. However, it is acknowledged that at the time of writing this document only a small proportion of interventions with botulinum toxin are following this process.

The GMMMG on behalf of Greater Manchester (GM) commissioners was tasked with scoping the uses of botulinum toxin in GM and reviewing available evidence in order to produce a commissioning policy including a clear set of criteria for each individual indication, and in effect facilitate the management of this tariff excluded high cost drug.

2. Purpose

The spend on botulinum toxin across GM amounts to an average of £1.4m per year¹, excluding private providers, which contributes to about 2% of the total CCG commissioned tariff excluded high cost drugs budget. The purpose of this policy is to ensure standardised 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 of this policy is pragmatic and recognises the widespread use of botulinum toxin in many specialties and the fact that treatment may continue long term.

2. Recommendations and criteria

2.1. 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.

2.2. People whose treatment with botulinum toxin is outside of this policy, 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.

2.3. Currently the funding mechanism for botulinum toxin is monitored approval. The usage of botulinum toxin and uptake of this policy will be reviewed after 12 months from publication. The providers should agree with commissioners on the method of demonstrating ongoing compliance with this policy. This should include discussion about resources needed for introduction and maintenance of the policy (e.g. use of Hi Cost Drugs Database Blueteq system, clinical audit).

2.4. Where specified in this policy and for all indications not contained in this document, botulinum toxin is not commissioned. Clinicians wishing to use botulinum toxin in such circumstances, must submit an Individual Funding Request (IFR) via the Effective Use of Resources (EUR) process. The request must state clinical exceptionality and include supporting information. The request must be approved by the responsible commissioner prior to starting the treatment.

2.5. The cost of treatment can only be recharged to the responsible commissioner if the provider has gained approval before starting treatment; either by assurance of compliance with this policy or via a successful IFR submission.

2.6. The policy considers patients treated in adult services unless otherwise specified.

¹ SLAM data supplied by GM NHS providers for 2015-2017 (data may be incomplete).

2.8. The table below lists uses of botulinum toxin and provides initiation criteria that patients must meet to obtain the treatment. Continuation criteria (including continuation of care for patients transferred from 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 below.

A. Spasticity

1a	Focal spasticity in adults	<p>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:</p> <p>(1) there is focal element to spasticity, and</p> <p>(2) spasticity is interfering with function or independence (e.g. mobility, communication, nutritional intake) and/or is painful, and</p> <p>(3) treatment is conducted by suitably experienced team (e.g. neuro-rehabilitation team, including consultant with appropriate skills and training), and</p> <p>(4) treatment goals and outcome measures are agreed and documented before treatment starts.</p>
1b	Spasticity in children	NHSE commissioned. Follow NHSE process for funding approval.

B. Movement disorders - including focal dystonias and facial nerve disorders

2	Upper limb dystonia	<p>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:</p> <p>(1) dystonia is interfering with function or independence (e.g. mobility, communication, nutritional intake) and/or is painful, and</p> <p>(2) other methods have not been successful or were not appropriate (e.g. physiotherapy, pharmacological treatment), and</p> <p>(3) treatment is conducted by suitably experienced team (e.g. neuro-rehabilitation team, including consultant with appropriate skills and training), and</p> <p>(4) treatment goals and outcome measures are agreed and documented before treatment starts.</p>
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3	Lower limb dystonia	<p>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:</p> <p>(1) dystonia is interfering with function or independence (e.g. mobility) and/or is painful, and</p> <p>(2) other methods have not been successful or were not appropriate (e.g. physiotherapy, pharmacological treatment), and</p> <p>(3) treatment is conducted by suitably experienced team (e.g. neuro-rehabilitation team, including consultant with appropriate skills and training), and</p> <p>(4) treatment goals and outcome measures are agreed and documented before treatment starts.</p>
4	Spasmodic torticollis (cervical dystonia)	<p>Botulinum toxin can be used for cervical dystonia, where patient experiences:</p> <p>(1) pain and/or functional impairment that include both of the following symptoms:</p> <p>(a) sustained head tilt or abnormal posturing resulting in pain and/or functional impairment, and</p> <p>(b) recurrent involuntary contraction of one or more muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, posterior cervical)</p>
5	Laryngeal dystonia (spasmodic dysphonia)	<p>Botulinum toxin can be used for spasmodic dysphonia, where:</p> <p>(1) dystonia is interfering with function or independence (e.g. communication, nutritional intake) and/or is painful, and</p> <p>(2) conservative measures (e.g. speech therapy) were tried and found ineffective.</p>
6	Cricopharyngeal dysfunction	<p>Botulinum toxin can be used for cricopharyngeal dysfunction where:</p> <p>(1) surgery is inappropriate (e.g. elderly), and</p> <p>(2) patient has dysphagia resulting in functional impairment due to upper oesophageal spasm, or</p> <p>(3) functional impairment post laryngectomy inclusive of dysphagia and/or voice loss.</p>
7	Palatal myoclonus	<p>Botulinum toxin can be used for symptomatic palatal myoclonus:</p> <p>(1) resulting in tinnitus or other disturbing experience disabling normal functioning, and</p> <p>(2) where oral pharmacological intervention with anticonvulsant or anxiolytic is inappropriate or ineffective,</p> <p>(3) other interventions e.g. white noise have not been successful.</p>
8	Oromandibular dystonia	<p>Botulinum toxin can be used for oromandibular dystonia where:</p> <p>(1) systemic medications ineffective or inappropriate (e.g. baclofen), and</p> <p>(2) patient has functional issues - pain or spasm and disfigurement, difficulties with feeding, or impaired dental care or malocclusion preventing swallowing or impairing speech.</p>

9	Blepharospasm	<p>Botulinum toxin can be used for blepharospasm:</p> <p>(1) associated with dystonia, and</p> <p>(2) there is evidence of functional and/or visual impairment.</p>
10	Meige's syndrome	<p>Botulinum toxin can be used for Meige's syndrome presenting as blepharospasm or oromandibular dystonia or both:</p> <p>(1) primary or secondary to brain lesion (not drug induced), and,</p> <p>(2) systemic medications ineffective or inappropriate (e.g. baclofen), and</p> <p>(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.</p>
11	Hemifacial spasm	<p>Botulinum toxin can be used for hemifacial spasm, where</p> <p>(1) there is evidence of functional and/or visual impairment.</p>
12	Post facial nerve palsy - hyperkinesis causing asymmetry and synkinesis	<p>Botulinum toxin can be used for patients with chronic, unresolved facial nerve palsy resulting in asymmetry and/or synkinesis, where:</p> <p>(1) there is evidence of functional impairment (e.g. communication, nutrition, pain due to disfigurement), and</p> <p>(2) permanent nerve damage cannot be managed by facial rehabilitation alone, and</p> <p>(3) where surgery not indicated or unsuccessful.</p> <p><u>Continuation criteria:</u></p> <p>(1) patient must still show functional issues returning after previous successful intervention with botulinum toxin.</p> <p>Botulinum toxin is <u>not commissioned</u> solely for appearance enhancement.</p>

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 <u>temporary</u> 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. <u>Discontinuation criteria:</u> Stop once corneal healing achieved or prevention no longer needed.
15	Dystonic brow spasm	Not commissioned. There is insufficient evidence to support use of botulinum toxin for dystonic brow spasm.
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 keratopathy secondary to entropion), and (2) where surgery is inappropriate or unlikely to resolve the issue as a single intervention.
18	Nystagmus	Not commissioned. 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	<p>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:</p> <p>(1) prism adaptation test predicts post-operative diplopia, to evaluate risk of making double vision worse or demonstrate potential for binocular vision.</p> <p>Note strabismus repair is considered aesthetic in adults with uncorrected congenital strabismus and no potential for binocular vision (no binocular fusion). Botulinum toxin is <u>not commissioned</u> solely for appearance enhancement.</p>
19b	Squint (strabismus) - adults and children – therapeutic	<p>Botulinum toxin can be used for strabismus in children and adults, where:</p> <p>(1) there is potential for binocular vision, such as acute onset esotropia, sixth nerve palsy and infantile esotropia, and</p> <p>(2) conservative treatment (prisms and/or exercises) fail, or</p> <p>(3) for medical management of cases unsuitable for surgery - e.g. where patient is not suitable for surgery for a clinical reason.</p> <p>Note strabismus repair is considered aesthetic in adults with uncorrected congenital strabismus and no potential for binocular vision (no binocular fusion). Botulinum toxin is <u>not commissioned</u> solely for appearance enhancement.</p>
20	Decompensating esophoria and decompensating exophoria	<p>Botulinum toxin can be used for decompensating heterophoria (esophoria or exophoria), where:</p> <p>(1) the patient is symptomatic, asymptomatic with foveal suppression or likely to decompensate and lose binocularity, and</p> <p>(2) there is record of functional and visual impairment, and</p> <p>(3) other treatments have been tried and failed (removal of environmental factors, correction or modification of refractive errors, orthoptic exercises, prisms), and</p> <p>(4) surgery is inappropriate or patient is unsuitable for surgery.</p> <p>Botulinum toxin is <u>not commissioned</u> solely for appearance enhancement.</p>

D. Gastrointestinal tract disorders

21	Salivary fistulas	<p>Botulinum toxin can be used for unresolving salivary fistulas, where:</p> <ul style="list-style-type: none"> (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	<p>Botulinum toxin can be used for unresolving sialoceles, where:</p> <ul style="list-style-type: none"> (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	<p>Botulinum toxin can be used for sialorrhea under following circumstances:</p> <ul style="list-style-type: none"> (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	<p>Botulinum toxin can be used for patients with achalasia who are:</p> <ul style="list-style-type: none"> (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 (type III)	<p>A <u>single dose</u> of botulinum toxin is commissioned as a diagnostic trial instead of manometry prior to sphincterotomy only for patients with suspected type III SOD. Repeated injections are not commissioned for SOD.</p>

26	Abdominal wall reconstruction	<p>Botulinum toxin can be used as one-off, preoperative, ultrasound guided injection in elective complex hernia patients where:</p> <ul style="list-style-type: none"> (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)	<p>A single dose of botulinum toxin is commissioned for patients meeting the following criteria:</p> <ul style="list-style-type: none"> (1) The anal fissure is chronic, and (2) The following symptoms are present: <ul style="list-style-type: none"> (a) pain on defecation and lasting afterwards, and/or (b) bleeding, and (3) The following treatments have been tried and were unsuccessful: <ul style="list-style-type: none"> (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)	<p>Botulinum toxin can be used for patients with anismus, where</p> <ul style="list-style-type: none"> (1) conservative measures were tried and failed, including: <ul style="list-style-type: none"> (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	<p>Botulinum toxin can be used for significant and intractable excessive sweating of axillae, where</p> <p>(1) hyperhidrosis not associated with social anxiety disorder or secondary to other underlying cause, and</p> <p>(2) there is a record of unsuccessful trial of:</p> <p>(a) conservative measures (lifestyle factors and avoidance of triggers), and</p> <p>(b) aluminium based topical treatment for at least 1-2 months.</p>
29b	Severe primary palmar hyperhidrosis	<p>Botulinum toxin can be used for significant and intractable excessive sweating of the palmar area:</p> <p>(1) hyperhidrosis not associated with social anxiety disorder or secondary to other underlying cause, and</p> <p>(2) there is a record of unsuccessful trial of:</p> <p>(a) conservative measures (lifestyle factors and avoidance of triggers) and</p> <p>(b) aluminium based topical treatment for at least 1-2 months or iontophoresis</p> <p>(c) treatment with systemic anticholinergic (preferably oxybutynin, off-label) was ineffective or not appropriate.</p>
29c	Severe primary plantar hyperhidrosis	<p>Botulinum toxin can be used for significant and intractable excessive sweating of the plantar area:</p> <p>(1) hyperhidrosis not associated with social anxiety disorder or secondary to other underlying cause, and</p> <p>(2) there is a record of unsuccessful trial of:</p> <p>(a) conservative measures (lifestyle factors and avoidance of triggers) and</p> <p>(b) aluminium based topical treatment for at least 1-2 months or iontophoresis, and</p> <p>(c) treatment with systemic anticholinergic (preferably oxybutynin, off-label) was ineffective or not appropriate.</p>
29d	Severe primary craniofacial hyperhidrosis	<p>Botulinum toxin can be used for significant and intractable excessive sweating of craniofacial area:</p> <p>(1) hyperhidrosis not associated with social anxiety disorder or secondary to other underlying cause, and</p> <p>(2) there is a record of unsuccessful trial of:</p> <p>(a) conservative measures (lifestyle factors and avoidance of triggers), and</p> <p>(b) aluminium based topical treatment for at least 1-2 months, and</p> <p>(c) treatment with systemic anticholinergic (preferably oxybutynin, off-label) was ineffective or not appropriate.</p>

29e	Severe generalised sweating	Not commissioned. There is insufficient evidence to support use of botulinum toxin for generalised hyperhidrosis.
30	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

31	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.
32	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 (c) surgery is not appropriate.

G. Pain syndromes

33	Refractory trigeminal neuralgia	<p>Botulinum toxin can be used in patients with refractory trigeminal neuralgia, where:</p> <p>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</p> <p>(2) surgery is inappropriate.</p>
34	Prophylaxis of headaches with chronic migraine (NICE TA260)	<p>Botulinum toxin can be used for chronic migraine, where:</p> <p>(1) patient experiences headaches on at least 15 days per month of which at least 8 are with migraine, and</p> <p>(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</p> <p>(3) other causative disorders have been ruled out, and</p> <p>(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.</p> <p><u>Continuation criteria:</u></p> <p>(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.</p> <p><u>Discontinuation:</u></p> <p>(1) chronic migraine changes to episodic (less than 15 days/month in 3 consecutive months), or</p> <p>(2) treatment not effective (max 2 cycles)</p>
35	Medication overuse headache	Not commissioned. There is insufficient evidence to support use of botulinum toxin for medication overuse headache.
36	Post-craniotomy pain	Not commissioned. 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	<p>Botulinum toxin can be used intravesically in patients with overactive bladder, who:</p> <ul style="list-style-type: none"> (1) have urodynamically confirmed detrusor over activity* (2) have received and not responded to a trial of conservative management including: <ul style="list-style-type: none"> (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): <ul style="list-style-type: none"> (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) <p><u>Continuation criteria:</u></p> <ul style="list-style-type: none"> (1) assessed at 3 months and (2) showing a 50% or greater improvement in continence episodes or urgency episodes per day <p><i>*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.</i></p>
37b	Neurogenic detrusor overactivity with urinary incontinence due to spinal cord disease or injury	<p>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:</p> <ul style="list-style-type: none"> (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.
<p>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.</p>		

I. Skin

38	Scar softening and modification	Not commissioned. There is insufficient evidence to support use of botulinum toxin for scar prevention, modification and softening.
39	Leaking (hyperactive) urostomy	Not commissioned. There is insufficient evidence to support use of botulinum toxin for leaking (hyperactive) urostomy.
40	Digital ulceration	NHSE commissioned. Use of botulinum toxin requires an IFR submitted to NHSE (outside of their policy).

3. Points for consideration:

3.1. 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).

3.2. 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.

3.3. 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.

3.4. 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 policy. Local protocols and/or up to date literature should be consulted for such practice.

3.5. 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.

4. 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)

5. 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
- Spasticity in adults: management using botulinum toxin. National Guidelines (2009).
- Royal College of Physicians Dystonia: A Guide to Best Practice. The dystonia society (2014)

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