

Oxfordshire¹ Clinical Commissioning Group Policy Statement

Policy No. 254b, (TVPC12) Botulinum Toxin A

Recommendation made by the Priorities Committee: **November 2014, January 2015, November 2019; APCO - July 2018, January 2020, March 2020**

Date agreed by OCCG: **23rd July 2020**

Date of issue: **14th Sept 2015, September 2018, July 2020**

Botulinum toxin type A is a purified neurotoxin complex, derived from the bacterium *Clostridium botulinum*, which has neuromuscular transmitter blocking effects.

The Thames Valley Priorities Committee (see TVPC12) has considered the evidence for use of Botulinum Toxin A for treatment of the following indications and recommends its use only where indicated in the table below (Thames Valley). Oxfordshire Area Prescribing Committee has considered additional indications (Oxfordshire only) and has come to an agreement with local clinicians in Oxford University Hospitals Foundation Trust **only**. All indications will be subject to audit.

Indication	Commissioning Policy/Criteria for use
Overactive Bladder (Thames Valley)	<p>Botulinum Toxin A is an option for the secondary management of overactive bladder refractory to conservative and non-interventional medical treatment providing that:</p> <ul style="list-style-type: none"> • Patients have been managed and treated according to the relevant NICE clinical guideline (CG). <i>CG 97² Lower urinary tract symptoms in men- management, CG 148³ Urinary incontinence in neurological disease: assessment and management and CG171⁴ Urinary incontinence in women: management.</i> • Patients have been supported with behavioural and lifestyle advice and a trial of at least two medications but have not had a positive response to these interventions. • A multidisciplinary team has considered Botulinum Toxin to be the most appropriate treatment. • Patients are willing and able to self-catheterise • Informed consent has been obtained

¹ See also Thames Valley Policy TVPC12 <http://www.fundingrequests.ccsu.nhs.uk/thames-valley-priorities-committee/>

² <http://www.nice.org.uk/guidance/CG97>

³ <http://www.nice.org.uk/guidance/CG148>

⁴ <http://www.nice.org.uk/guidance/CG171>

Chronic migraine (Thames Valley)	<p>Botulinum toxin A is a treatment option for patients with chronic migraine in line with NICE <i>Guidance for the Prophylaxis of Headaches in Adults with Chronic Migraine</i>, TA260⁵ (2012). This is defined as headaches on at least 15 days per month of which at least 8 days are with migraine:</p> <ul style="list-style-type: none"> • that has not responded to at least three prior pharmacological prophylaxis therapies <p>AND</p> <ul style="list-style-type: none"> • the condition is appropriately managed for medication overuse. <p>In all other clinical circumstances, Botulinum toxin type A is not normally funded for chronic migraine treatment.</p>
Spasticity (Thames Valley)	<p>Botulinum Toxin A is a treatment option for Spasticity in children and young people with non-progressive brain disorders and for spasticity in adults in line with NICE <i>Guidance for Spasticity in children and young people</i>, CG145⁶ (2012) and RCP <i>Guidance for Spasticity in adults: management using botulinum toxin</i> (2009)⁷.</p> <ul style="list-style-type: none"> • Spasticity in adults in upper or lower limb including stroke, and with focal or multifocal spasticity, where there is a dynamic spastic component (as opposed to contracture) in line with Royal College of Physicians 2009 National Guidance. There should be clearly identified goals for treatment and anticipated functional gains. Botulinum injection therapy should be used as part of a rehabilitation programme. • Focal spasticity: Treatment of dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients in line with NICE CG145.
Chronic Anal fissure (Thames Valley)	<p>Botulinum Toxin A is not normally funded for chronic anal fissures on grounds of lack of high quality evidence of clinical and cost effectiveness: Thames Valley Priorities Committee statement.</p>
Long term Bell's Palsy (Thames Valley)	<p>Botulinum Toxin A is not normally funded for long term Bell's Palsy on grounds of lack of high quality evidence of clinical and cost effectiveness.</p>
Sialorrhoea (Severe drooling, hypersalivation) (Thames Valley)	<p>Botulinum Toxin A is a treatment option for chronic sialorrhoea caused by neurological conditions in adults. This is in line with NICE TA 605 Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea.</p>

⁵ <http://www.nice.org.uk/guidance/ta260>

⁶ <http://www.nice.org.uk/guidance/cg145>

⁷ <https://www.rcplondon.ac.uk/sites/default/files/documents/spasticity-in-adults-management-botulinum-toxin.pdf>

<p>Achalasia (Oxfordshire only)</p>	<p>Dysphagia (with or without aspiration into lungs) along with findings on barium swallow and/or oesophageal manometry that support the diagnosis. Considered eligible for oesophago-gastroduodenoscopy OGD and gastro-oesophageal junction botulinum toxin A injection if the following criteria are met (upto 4 doses per year):</p> <p>Criteria for use</p> <ul style="list-style-type: none"> • Failure to control with GTN spray or nifedipine (assess over approx 4 weeks) or; • unsuitable for endoscopic balloon dilatation. Includes patients who are not fit for surgery (e.g. The elderly or those with significant comorbidities) or those not suitable for balloon dilatation (e.g. frail or elderly, especially those at increased risk death should they have an oesophageal perforation). • Discontinue treatment in patients who do not respond after one dose (100 units). Note: The failure rate of botulinum toxin is <10%.
<p>Anal achalasia, Hirschprung, Chronic constipation (Oxfordshire only)</p>	<p>For hyperactive anal sphincter and relaxation of sphincter for withholding of defaecation in severe constipation. Main usage in Hirschprung's disease where hyperactive sphincter causes post-operative faecal loading. Application of Botox (max 3 injections per patients) prevents anal stretch procedure which can lead to sphincter damage and also avoids strip excision of the sphincter site. Also for ultrashort Hirschprung's disease whereby an operation may be avoided.</p> <p>Criteria for use:</p> <ul style="list-style-type: none"> • Intractable constipation not responding to laxatives. • Seen by surgeons and physicians.
<p>Spasmodic Dysphonia (Oxfordshire only)</p>	<p>Injection of botulinum toxin type A into laryngeal muscles under electromyography guidance (EMG) for patients with moderate/severe spasmodic dysphonia unresponsive to speech therapy (Max 2-4 doses)</p> <p>Criteria for use:</p> <ul style="list-style-type: none"> • Assessment in Multidisciplinary Voice Clinic, to confirm diagnosis of spasmodic dysphonia • Compensatory techniques and therapy with Speech Therapy • Moderate/severe on GRBAS (validated speech therapy tool) • No benefit received from course of Speech Therapy • Disabling symptoms
<p>Ophthalmic Focal Dystonia (hemifacial spasm, blepharospasm) (Oxfordshire only)</p>	<p>Blepharospasm is a focal dystonia of the orbicularis oculi muscle which causes uncontrollable blinking and closure of the eyelids. Blepharospasm is understood to be abnormal functioning of the basal ganglia for control of movement. Botulinum toxin injections, which weaken orbicularis oculi, are the most effective treatment.</p> <p>Hemifacial spasm is usually caused by compression of the 7th cranial nerve. This tends to be much less disabling but may cause considerable distress and embarrassment with psychiatric problems. Patients affected with these disorders are often mistakenly considered to have psychiatric problems.</p>

Although the two disorders are quite distinct physiologically, therapy with botulinum toxin has proven very effective in both.

Criteria for use:

- A confirmed diagnosis of Blepharospasm/ Hemifacial Spasm by the Consultant Ophthalmologist
- Spasmodic and uncontrollable spasms of the orbicularis oculi muscle meaning that the patient cannot keep their eyes open
- Botulinum Toxin treatment will be stopped if the patient proves to be a consistent non responder, develops an allergy or has re current side effects/ intolerance which cannot be determined.

Individual preparations are not interchangeable with other preparations. The preparation with the lowest acquisition cost is recommended within licensed indications. MHRA Drug Safety Update: Products that contain botulinum toxin are associated with the risk of serious adversereactions due to distant spread of toxin.

NOTES:

- Potentially exceptional circumstances may be considered by a patient's CCG where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living) and there is evidence that the intervention sought would improve the individual's health status.
- This policy will be reviewed in the light of new evidence or new national guidance, e.g., from NICE.
- Thames Valley clinical policies can be viewed at <http://www.fundingrequests.ccsu.nhs.uk/>
- Oxfordshire CCG clinical polices can be viewed at <http://www.oxfordshireccg.nhs.uk/professional-resources/policies.htm>