

Thames Valley Priorities Committee Commissioning Policy Statement

Policy No. TVPC 12 Botulinum Toxin A

**Recommendation made by
the Priorities Committee: November 2014/ January 2015**

Date of issue: August 2015

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 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.

Indication	Commissioning Policy
Overactive Bladder	<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. NICE clinical guideline 97¹ refers to the management of lower urinary tract symptoms in men. NICE clinical guideline 148² refers to the management of lower urinary tract dysfunction in patients with neurological diseases. NICE clinical guideline 171³ relates to the management of urinary incontinence in women. • 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
Chronic migraine	<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>, TA260⁴ (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>

¹ <http://www.nice.org.uk/guidance/CG97>

² <http://www.nice.org.uk/guidance/CG148>

³ <http://www.nice.org.uk/guidance/CG171>

⁴ <http://www.nice.org.uk/guidance/ta260>

	<ul style="list-style-type: none"> whose 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	<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>, CG145⁵ (2012) and RCP <i>Guidance for Spasticity in adults: management using botulinum toxin</i> (2009)⁶.</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 spasticity CG145 guidelines.
Chronic Anal fissure	Botulinum Toxin A is not normally funded for chronic anal fissures on grounds of lack of high quality evidence of clinical and cost effectiveness.
Long term Bell's Palsy	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.
Sialorrhoea (Severe Drooling)	Botulinum Toxin A is not normally funded for severe drooling on grounds of lack of high quality evidence of clinical and cost effectiveness.

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 adverse reactions 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 policies can be viewed at <http://www.oxfordshireccg.nhs.uk/professional-resources/priority-setting/lavender-statements/>

⁵ <http://www.nice.org.uk/guidance/cg145>

⁶ <https://www.rcplondon.ac.uk/sites/default/files/documents/spasticity-in-adults-management-botulinum-toxin.pdf>